KnightStar® 330

Service Manual

Bi-Level® Ventilator

Y-102942-00A Rev G
March, 2004

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The ventilator should be operated and serviced only by trained professionals. Puritan Bennett's sole responsibility with respect to the ventilator, and its use, is as stated in the limited warranty provided.

Nothing in this manual shall limit or restrict in any way Puritan Bennett's right to revise or otherwise change or modify the equipment (including its software) described herein, without notice. In the absence of an express, written agreement to the contrary, Puritan Bennett has no obligation to furnish any such revisions, changes, or modifications to the owner or user of the equipment (including its software) described herein.

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SECTION 1

General information

This manual provides information needed to service the Puritan Bennett *KnightStar 330*® Bi-Level® ventilator and is intended for use by certified biomedical engineering technicians or personnel with equivalent experience and training in servicing this type of equipment.

This section provides introductory information on the *KnightStar 330* ventilator including:

- General safety information
- Instructions on how to use the manual
- A description of the ventilator, its accessories, and its controls and indicators
- Detailed specifications and required tools and test equipment used for service and repair

1.1 Safety considerations

Please take the time to familiarize yourself with the following caveats as they cover safety considerations, special handling requirements, and regulations that govern the use of the *KnightStar 330* ventilator.

- To ensure proper servicing and avoid the possibility of physical injury, only qualified personnel (minimum requirement Certification for Biomedical Equipment Technician or equivalent) should attempt to service or make authorized modifications to the ventilator.

  The user of this product shall have sole responsibility for any ventilator malfunction due to operation or maintenance performed by anyone not trained by Puritan Bennett staff.
- To avoid an electrical shock hazard while servicing the ventilator, be sure to remove all power to the ventilator by turning off the ventilator power switch and disconnecting the power source.
- To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (e.g., flammable anesthetics and/or heaters) away from the *KnightStar 330* and oxygen hoses.

  Do not use oxygen hoses that are worn, frayed, or contaminated by combustible materials such as grease or oils. (Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.)

  In case of fire or a burning smell, immediately disconnect the ventilator from the oxygen supply, and the power source.
- When handling any part of the *KnightStar 330*, always follow your hospital infection control guidelines for handling infectious material.

  Puritan Bennett recognizes that cleaning, sterilization, sanitation, and disinfection practices vary widely among healthcare institutions. It is not possible for Puritan Bennett to specify or require specific practices that will meet all needs, or to be responsible for the effectiveness of cleaning, sterilization, and other practices carried out in the patient care setting. Specific cleaning instructions for the *KnightStar 330* are given in section 5.2 on page 1.

  Puritan Bennett recommends that users of its products that require cleaning and sterilization/disinfection consider the Center for Disease Control (CDC) publication:

Guidelines for Prevention of Nosocomial Pneumonia available from the CDC Web site: http://www.cdc.gov/publications.htm. Refer to the table on page 1-23 for a list of approved disinfectants and cleaning agents.

- Patients on ventilation equipment should be appropriately monitored by competent medical personnel and suitable monitoring devices.
- For a thorough understanding of ventilator operations, be sure to thoroughly read this manual and the *KnightStar 330 Clinician's Manual* before operating the device. These manuals provide service, repair, and technical information concerning the operation and performance of the ventilator.
- Before patient use, be sure to check the equipment for proper operation.
- Do not use sharp objects to make selections on the keypad.
- Check the ventilator periodically as outlined in this manual; do not use if defective. Immediately replace parts that are broken, missing, obviously worn, distorted, or contaminated.
- Federal law (U.S.) restricts this device to sale by or on the order of a physician.

1.2 Electromagnetic susceptibility

The *KnightStar 330* equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2001 (or Medical Device Directive 93/42/EEC). This testing shows that the device provides reasonable protection against harmful interference in a typical medical installation. There is, however, no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively affected by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or relocate the devices
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Contact the manufacturer or your local representative for help

1.3 Customer assistance

For further assistance, or for questions regarding the applicability of the information in this manual, contact Puritan Bennett Technical Support at 1.800.255.6774 (within the USA) or your local Puritan Bennett representative (outside the USA).

1.4 How to use this manual

While this manual covers the ventilator configurations currently supported by Puritan Bennett, some product upgrades may be available prior to a corresponding revision of this manual. The current revision of this manual is available on the Internet at: http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/PBProductManuals.html.

Puritan Bennett recommends that you become familiar with this manual and the *KnightStar 330 Clinician's Manual* before attempting to operate or service the ventilator. These manuals provide service, repair, and technical information concerning the operation and performance of the Puritan Bennett *KnightStar 330* bi-level ventilator.

1.4.1 Definitions

This manual uses three special indicators to convey information of a specific nature. They include:

Warning

Indicates a condition that can endanger the patient or the ventilator operator.

Caution

Indicates a condition that can damage the equipment or other property.

NOTE:

Indicates points of particular interest that make operation of the ventilator more efficient or convenient.

1.4.2 Using the manual to troubleshoot the *KnightStar 330*

NOTES:

- At a minimum, the repair technician should be a Certified Biomedical Equipment Technician (CBET) or possess equivalent experience and training before performing any of the service instructions described in this manual
- Due to specific design interactions between the Main PCBA, blower, and pitot tube, individual field replacement of any of these parts is not possible. If required, please return the *KnightStar 330* to a Puritan Bennett factory service center for repair.

1. Refer to Section 4 of this manual to diagnose the problem. Using the troubleshooting guides in this section, determine if the problem can be corrected without returning the device to a factory service center.
2. Use Table 1-14 to identify and order the required service parts.
3. Follow instructions in Section 5 to disassemble, repair, and reassemble the *KnightStar 330*.
4. Perform and document performance verification tests described in Section 3.

1.5 General product description

The Puritan Bennett *KnightStar 330* is a continuous, bi-level ventilator that provides noninvasive ventilation for the treatment of respiratory insufficiency and obstructive sleep apnea that may occur in the home. It is also indicated for the treatment of respiratory failure in institutional environments. It is intended to assist the ventilation of spontaneously breathing patients who are over 30 kg (66 lb) in weight.

The *KnightStar 330* is a microprocessor-controlled pressure generator capable of monitoring the air flow and controlling the pressure delivered to the patient. The following are some of its operating features:

- Provides three breathing modes, including Continuous Positive Airway Pressure (CPAP), Inspiratory/Expiratory Positive Airway Pressure (I/E PAP), and Assist Control (A/C).
- Monitors pressure, tidal volume, respiratory rate, air leaks, peak flow, and I:E ratio.

- Provides precise respiratory support and patient comfort via adjustable inspiratory and expiratory trigger sensitivity.
- Uses audible and visual indicators to alert users to power failure, system leaks, and other conditions that could affect device performance.
- Allows a maximum pressure setting of 30 cmH_2O, with a pressure limitation of 40 cmH_2O for a single-fault condition.
- Compensates for delivered pressure within specification for altitudes from 0 to 8,000 feet (2438 meters) at 3 to 30 cmH_2O, and compensates for leaks up to 60 liters per minute.

1.6 Configuration information

The *KnightStar 330* is available in six configurations—North American and five international versions. The major differences between ventilators are listed below:

North American: The North American version has Mode and Settings control panel keys and some displayed information identified in English, and includes English labels, software, and manuals. The power cord provided fits a standard 115 V AC outlet. Alarm volume may be set from 0 (off) to 3 (maximum).

All other versions: All versions of the *KnightStar 330* other than North American have control panel keys and displayed information identified using symbols. Labels, software and manuals are provided in various language configurations. A power cord with the appropriate plug end is provided according to the configuration ordered. Alarm volume may be set from 0 (off) to 3 (maximum), except for Japanese. The Japanese *KnightStar 330* alarm volume may be set from 1 (minimum) to 3 (maximum) and cannot be set to "off."

Figure 1-2 on page 1-12 shows the *KnightStar 330*'s control panel.

1.7 Accessories

The following accessories are either required or can be used with the *KnightStar 330*. See Table 1-1 for ordering information.

Calibration Shell: The calibration shell is required for Performance Verification testing on the *KnightStar 330*.

Patient circuit: Puritan Bennett recommends using the KnightStar 330 with 1.8 m (6 ft) or 2.4 m (8 ft) tubing and approved interfaces.

Oxygen Adapter: An optional O_2 adapter may be connected to the *KnightStar 330* outlet port or outlet air filter to enable the use of supplemental oxygen. Refer to the *KnightStar 330 Clinician's Manual* for more information.

Humidification device: The *KnightStar 330* supports the use of an optional Fisher & Paykel HC100 Humidifier, or equivalent.

External Battery: The *KnightStar 330* may be powered by an external battery. A 32 ampere-hour or a 7 ampere-hour battery are available. Separate cables are required to connect the *KnightStar 330* to an external battery or to a car or truck cigarette lighter outlet.

Other accessories: A carrying case and rolling stand are also available for the *KnightStar 330*.

Table 1-1 lists the ordering information for *KnightStar 330* accessories.

Table 1-1: *KnightStar 330* accessories

Description	Part number
Calibration Shell	S-231702-00B
KnightStar 330 Patient tube, 6 ft	Y-261000-27
KnightStar 330 Patient tube, 8 ft	Y-261000-30
Oxygen Adapter	Y-616155-03B
Passover humidifier kit (includes 13 in. hose, base, and reservoir)	Y-102938-00
Battery Kit, 32 Ampere-hour, Domestic (includes battery, case, 115 VAC charger, charger cable)	Y-CGVPD
Battery Kit, 32 Ampere-hour, European (includes battery, case, 220 VAC charger, charger cable)	Y-CGVPE
Battery Kit, 7 Ampere-hour (includes battery, case, universal charger, charger cable)	Y-CGVP7120
Cable, battery adapter	Y-102914-00
Cable, cigarette lighter adapter	Y-102913-00
Carrying Case, *KnightStar 330*	Y-213531-01
Rolling Stand, *KnightStar 330*	902284

1.8 Specifications

Table 1-2 lists the technical specifications of the *KnightStar 330* ventilator.

Table 1-2: Ventilator specifications

Physical characteristics	
Weight	1.21 kg (2.7 lb)
Dimensions	9.52 cm x 20.95 cm x 14.27 cm (3.75 in x 8.25 in x 5.62 in)
Air Outlet Port Connector	Standard 22-mm conical male
Device Airway Volume	65 mL
Patient Circuit Volume	695 mL (1.8 m/6 ft) 927 mL (2.4 m/8 ft)
Environmental specifications	
Temperature and Humidity	Operating: 5 to 40 °C (41 to 104 °F) at 15 to 95% relative humidity, noncondensing Storage: -40 to 70 °C (-40 to 158 °F) at 10 to 95% relative humidity, noncondensing
Altitude	Operating: 0 to 2438 m (0 to 8,000 ft)

Table 1-2: Ventilator specifications (continued)

Performance specifications	
Working Pressure	3 to 30 cmH_2O (1 cmH_2O = 0.098 kPa)
Pressure Limit	40 cmH_2O
Static Flow Pressure Regulation	For flow rates up to 60 L/min: CPAP ± 0.5 cmH_2O for settings from 4 to 20 cmH_2O Bi-level ± 1.0 cmH_2O for settings from 4 to 30 cmH_2O
Noise	≤ 30 dBA for IPAP/EPAP = 10 cmH_2O (measured 1 m in front of device)
Electrical specifications	
Rated Mains/AC Input Voltage	100 – 240 V AC nominal (85 – 264 V AC operating range)
Rated Input Frequency	50 – 60 Hz
Rated Input Power	140 W
Displayed Patient Parameter Accuracy	
Tidal Volume (Vt)	± 20 mL +20% of reading (between 50 mL and 2000 mL)
Peak Flow ($\dot{V}$)	± 5 LPM +20% of reading (between 1 and 100 LPM)
Leak (L)	± 5 LPM +20% of reading (between 1 and 100 LPM)
Respiratory Rate	± 1 BPM (between 1 and 50 BPM)
I:E Ratio	± 15% of reading (between 1:1 and 1:9.9)
Pressure	± 1 cmH_2O + 10% of reading (3 to 35 cmH_2O)
Circuit Resistance	
Inspiratory	0.2 cmH_2O at 30 L/min 0.9 cmH_2O at 60 L/min
Expiratory	4.1 cmH_2O at 30 L/min 5.0 cmH_2O at 60 L/min
External Battery Specifications	
Rated Input Voltage	12 V DC
Rated Input Current	6.0 A
Rated Input Power	140 W
Operating Time	32 Ampere-hour: approximately 8 hours 7 Ampere-hour: approximately 3 hours **NOTE:** Actual usage times depend upon patient's prescription settings.

Table 1-2: Ventilator specifications (continued)

Communication Port Specifications	
Communication capabilities	**RS-232 (serial) port** (Figure 1-1). A 9-pin female connector provides for RS-232 serial communications, I/E PAP digital triggering, and calibration EEPROM programming. The RS-232 function operates at signal levels of at least 3 V into a standard load at a data rate of 9.6 kbps and 19.2 kbps. Pin 9 is used for calibration EEPROM programming at the manufacturing and service sites, and during normal bi-level operation, supplies a 0 or 5-volt signal indicating a respective exhalation or inhalation trigger. Applying 24 ± 1 V to pin 9 enables the write function of the calibration EEPROM (U3). Any voltage less than 15 V will not enable the EEPROM write function. The calibration EEPROM contains calibration constants including those for flow and pressure control.

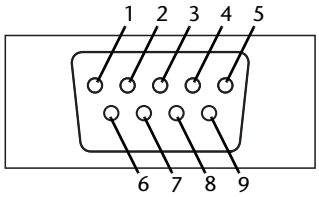


Figure 1-1. *KnightStar 330* RS-232 serial port pinout

NOTES:

- The RS-232 connector on devices manufactured prior to the year 2004 is rotated 180° from the configuration shown above.
- If you would like to use the *KnightStar 330* in a special application requiring serial communications, contact Puritan Bennett Technical Support at 1.800.255.6774 or your local Puritan Bennett representative.

Pin	Signal
1	Not connected
2	Transmit data (TxD) to PC
3	Receive data (RxD) from PC
4	Not connected
5	Ground (GND)
6	Not connected
7	Not connected
8	Not connected
9	Dual use I/E PAP trigger-out and program-enable input

1.9 Compliance and approvals

The *KnightStar 330* was developed in accordance with pertinent FDA guidances and North American and ISO international standards (Table 1-3). The manufacturing facility for this product is ISO 13485 certified.

The ventilator's IEC 60601-1/EN 60601-1 classification is Protection class II, Type BF, externally powered, IPX1 drip-proof equipment.

Table 1-3: Compliance with standards

Standard Type	Standard Number	Description
Quality system	EN ISO 13485:2000	Quality Systems – Medical Devices – Particular Requirements for the application of EN ISO 9001:1994
FDA Guidance	FDA Ventilator Guidance	FDA Reviewer Guidance for Ventilators, Draft (July 1995)
	FDA Medical Electrical Safety Guidance	FDA Reviewer Guidance for Pre-market Notification Submissions, November 1993 draft, Anesthesiology and Respiratory Devices Branch
Safety, USA	UL 2601-1	Medical Electrical Equipment, General Requirements for Safety, (2nd Edition)
Safety, Canada	CAN/CSA C22.2 No. 601.1- M90	Safety of Medical Electrical Equipment, General Requirements (Supplement 1:1994), (A2:1998)
Safety, Europe & International	EN 60601-1 (compliant with all applicable collateral standards and particular requirements)	Medical Electrical Equipment, Part 1: General Requirements for Safety, 1st Edition, 1988. (A1:1993), (A2:1995)
	EN 60601-1-1	Collateral Standard: Safety Requirements for Medical Electrical Systems, 2nd Edition, 2001
	EN 60601-1-2 (compliant with all applicable tests)	Medical Electrical Equipment, Collateral Standard: EMC – Requirements and Test, 2nd Edition, 2001
	JIST-1001-1	Safety Requirements for Medical Electrical Equipment in Japan
	CISPR 11	EMC Disturbance Characteristics – Limits and Methods of Measurement, Industrial Scientific and Medical (ISM) RF Equipment, Edition 3.1, 1999-08
	EN 475	Electrically generated alarm signals
This device complies with the requirements of Medical Device Directive 93/42/EEC concerning medical devices. CE 0123		

1.10 Breathing modes and settings

The *KnightStar 330* offers three breathing modes: CPAP, I/E PAP, and A/C. Each breathing mode enables a different set of system settings. Table 1-4 lists the modes and the adjustable settings within each mode. Table 1-5 describes each setting, its adjustable range, and how the setting can be accessed.

Table 1-4: Adjustable settings in each breathing mode

CPAP	I/E PAP	A/C
CPAP	IPAP	IPAP
Alarm volume	EPAP	EPAP
Leak alarm	Inspiratory sensitivity	Respiratory rate and backup respiratory setting (f)
Delay time	Expiratory sensitivity	I:E ratio
Ramp duration	Rise time	Inspiratory sensitivity
Ramp start pressure	Alarm volume	Expiratory sensitivity
Mask leak	Leak alarm	Rise time
	Low pressure alarm	Alarm volume
	High pressure alarm	Leak alarm
	Delay time	Low pressure alarm
	Ramp duration	High pressure alarm
	Ramp start pressure	Delay time
	Mask leak	Ramp duration
		Ramp start pressure
		Mask leak

Table 1-5: *KnightStar 330* settings, ranges, and accessibility

Setting	Description	Range	Accessibility
CPAP	Level of CPAP pressure	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
IPAP	Pressure during inspiration	3–30 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
EPAP	Pressure during expiration	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
Backup respiratory rate	Rate of machine-initiated breaths	3–30 bpm (increments of 1 bpm)	Top panel, RS-232
I:E ratio	Ratio of inhalation time to exhalation times for backup breath rate	1:1.0 to 1:4.0 (increments 0.5)	Top panel, RS-232
Inspiratory sensitivity	Sensitivity at which devices switches from EPAP to IPAP	1–5 (1 most sensitive; 5 least sensitive)	Top panel, RS-232

Table 1-5: *KnightStar 330* settings, ranges, and accessibility (continued)

Setting	Description	Range	Accessibility
Expiratory sensitivity	Sensitivity at which devices switches from IPAP to EPAP	1–5 (1 most sensitive; 5 least sensitive)	Top panel, RS-232
Rise-time	Rate of pressure increase	1–5 (1 is the fastest setting; 5 is the slowest)	Top panel, RS-232
Alarm volume	Sets the loudness of the alarm. **NOTE:** The alarm volume cannot be turned off on Japanese versions of the *KnightStar 330*.	0–3 (0=Off, 3=loudest) Japanese configuration only: 1–3 (1=lowest volume, 3=highest volume)	Top panel, RS-232
Leak alarm	Rate of air leaking at which alarm sounds	50–100 liters per minute (increments of 10 L/min); 0=Off	Top panel, RS-232
Low pressure alarm	Pressure below the prescribed IPAP setting at which an alarm will sound	1 cmH_2O below the IPAP setting to 1 cmH_2O above EPAP (in increments of 1 cmH_2O); 0 = Off.	Top panel, RS-232
High pressure alarm	Pressure above the prescribed IPAP setting at which an alarm will sound	1 cmH_2O above the IPAP setting to 35 cmH_2O (in increments of 1 cmH_2O); 0 = Off.	Top panel, RS-232
Delay time	Time delay before device automatically starts	0–30 minutes (in increments of 5 minutes)	Top panel, RS-232
Ramp duration	Time from device start to prescribed operating pressure	0–30 minutes (increments of 5 minutes)	Top panel, RS-232
Ramp start Pressure	Pressure at which the device starts ramp sequence	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
Interface (Mask) leak/ type	Patient interface purge hole leak rate	1–6 (1 is the lowest leak value, and 6 is the highest)	Top panel, RS-232
Patient ID	Unique patient identifier	12 digits	RS-232
Internal Clock	Clock used by device	24-hour clock	RS-232

NOTE: For information on using the RS-232 port, contact Puritan Bennett Technical Support at 1.800.255.6774 or your local Puritan Bennett representative.

1.11 Initial factory settings

The *KnightStar 330*'s initial factory settings are listed in Table 1-6.

Table 1-6: Initial factory settings

Setting	Value
MODE	A/C
IPAP	5 cm H_2O (same setting for CPAP)
EPAP	3 cm H_2O
Respiratory rate	10
I:E ratio	1:2.0
I Sensitivity	3
E Sensitivity	3
Rise time	3
Alarm volume	3
Leak alarm	100 L/min
Low pressure alarm	4 cmH_2O
High pressure alarm	6 cmH_2O
Delay time	0
Ramp duration	0
Ramp start pressure	3 cm H_2O
Mask leak	2
Over-pressure alarm	40 cmH_2O (not adjustable)

1.12 Controls, indicators, and symbols

Refer to Figure 1-2 through Figure 1-4 and Table 1-7 through Table 1-10 for ventilator controls, indicators, and symbols.

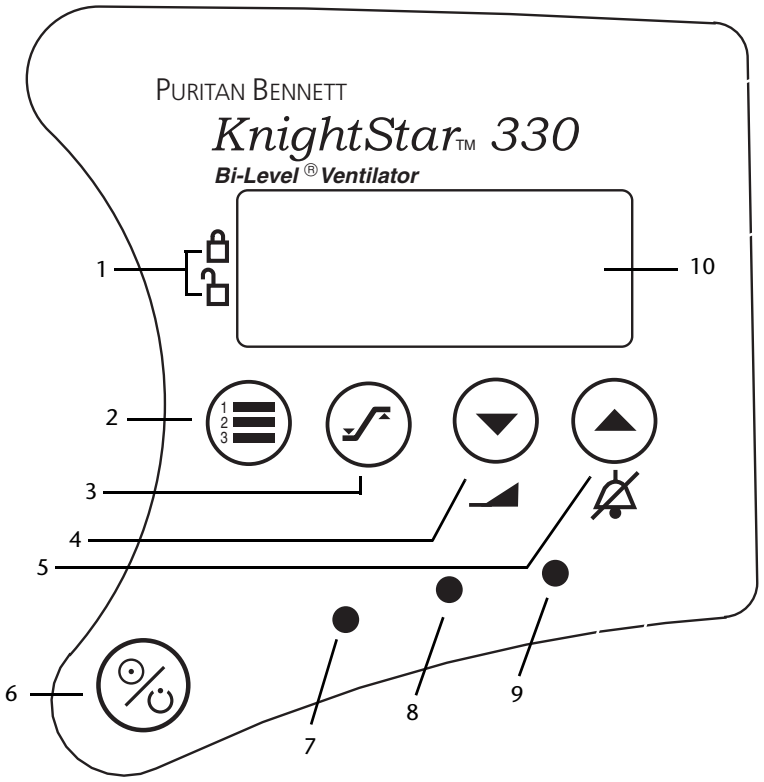


Figure 1-2. *KnightStar 330* Control Panel (International version shown above, North American version shown below)

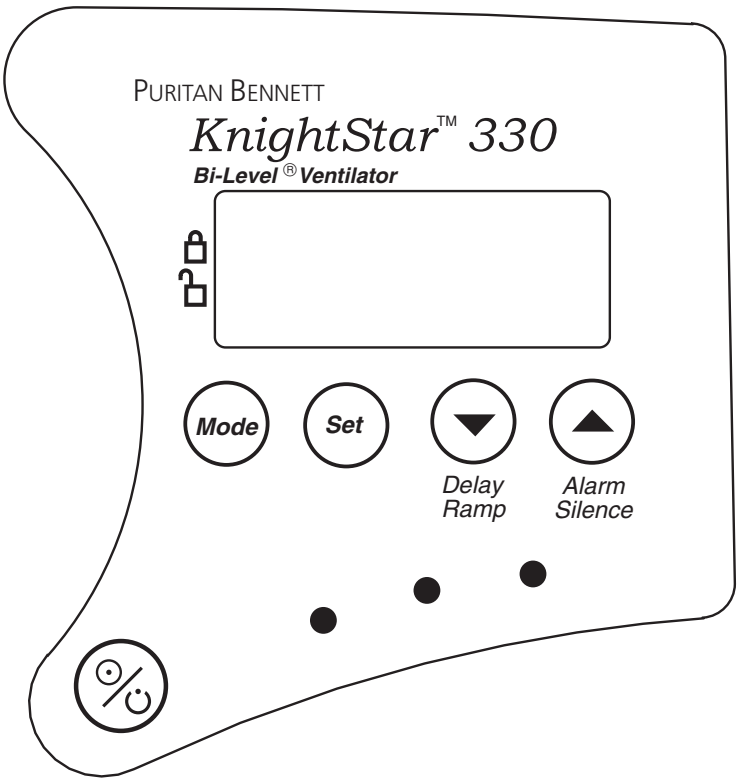


Table 1-7: *KnightStar 330* control panel keys and indicators

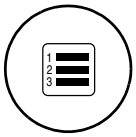
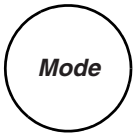
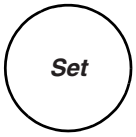
Index (Figure 1-2 on page 1-12)	Labeling	Function
1		Lockout Mode Indicator.  Indicates the *KnightStar 330* control panel is locked. In Lockout mode, the patient can change only the delay time, ramp duration, and start pressure settings.  Indicates the *KnightStar 330* control panel is unlocked. When Lockout mode is inactive, the clinician may change any ventilator settings. **NOTE:** To change the Lockout state, press and hold the Mode and Up Arrow keys simultaneously for approximately 2 seconds.
2	 International *or*  North American	Mode key. Pressing the Mode key repeatedly allows you to scroll through CPAP, I/E, and A/C modes. Press the Mode key to leave Settings mode when finished adjusting settings. The Mode key does not function when the *KnightStar 330* control panel is locked.
3	 International version *or*  North American version	Settings key. Press the Settings key repeatedly to scroll through available parameters for each breathing mode. When the *KnightStar 330* control panel is locked, the Settings key can only be used to change the delay time, ramp duration, and ramp start pressure.

Table 1-7: *KnightStar 330* control panel keys and indicators (continued)

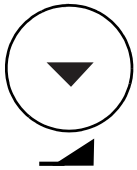
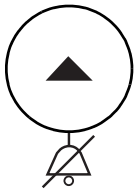
Index (Figure 1-2 on page 1-12)	Labeling	Function
4	 International version *or*  *Delay* *Ramp* North American version	Down Arrow & Delay/Ramp key. Use the Down Arrow key to decrease a selected setting value in Settings mode. If not in Settings mode, use this key to start or stop the Delay/Ramp function.
5	 International version *or*  *Alarm* *Silence* North American version	Up Arrow & Alarm Silence key. Use the Up Arrow key to increase a selected setting value in Settings mode. If not in Settings mode, use this key to mute an active alarm for one minute. **NOTE:** In A/C or I/E mode, when the main display screen is shown, pressing this key displays V̇ and I:E ratio if there are no active alarms.
6		On/Off key. Turn the *KnightStar 330* system on with a quick press and release action. To turn the device off, press and hold the On/Off key for 3 seconds. The *KnightStar 330* retains in memory the prescription settings last entered.
7	Green LED	When illuminated, indicates the presence of power, whether from Mains/AC or external battery (Stand-by mode).

Table 1-7: *KnightStar 330* control panel keys and indicators (continued)

Index (Figure 1-2 on page 1-12)	Labeling	Function
8	Yellow LED	When steadily illuminated and accompanied by the ***f*** ⭳ symbol displayed in the lower left corner of the LCD panel, indicates a LOW PRIORITY alarm condition. When steadily illuminated, with no symbol displayed on the LCD panel, indicates a full compliance log (see Table 4-4 on page 4-11). When flashing, indicates a MEDIUM PRIORITY alarm condition accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds). Refer to Section 4 for causes and corrections for alarm conditions.
9	Red LED	When flashing, indicates a HIGH PRIORITY alarm condition accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds). Refer to Table 4 for causes and corrections for alarm conditions.
10	Liquid Crystal Display (LCD)	The LCD provides an easy-to-read format for mode, settings, and patient data. A backlight illuminates the display when the Mode, Settings, or Up arrow key is pressed. The display will remain illuminated for approximately 60 seconds after the last key is pressed.

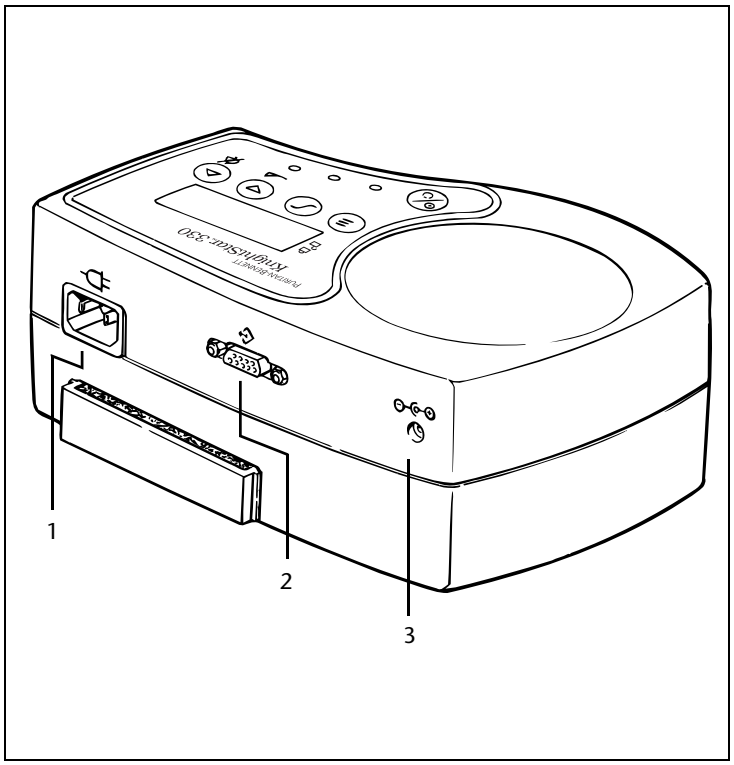


Figure 1-3. *KnightStar 330* rear view

Table 1-8: *KnightStar 330* rear view

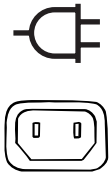
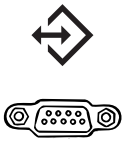
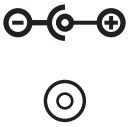
Index (Figure 1-3 on page 1-16)	Labeling	Function
1		Mains/AC power electrical input connector. The *KnightStar 330* operates on 100V to 240 V AC at 50 or 60 Hz.

Table 1-8: *KnightStar 330* rear view (continued)

Index (Figure 1-3 on page 1-16)	Labeling	Function
2		RS-232 (serial) port. The *KnightStar 330* is capable of serial communications with other devices such as a personal computer (PC). Contact your Puritan Bennett representative for more information. **NOTE:** PCs used with the *KnightStar 330* must meet regulatory standards for Safety of Information Technology Equipment (i.e. UL 60950 or EN 60950). Available from many sources, these standards specify requirements intended to reduce risks of fire, electrical shock, and injury to the operator or service person who comes into contact with the equipment.
3		External battery connector. Used for connecting an optional external 12 V DC battery, or for use with a 12 V automobile cigarette lighter adapter when Mains/AC power is not available.

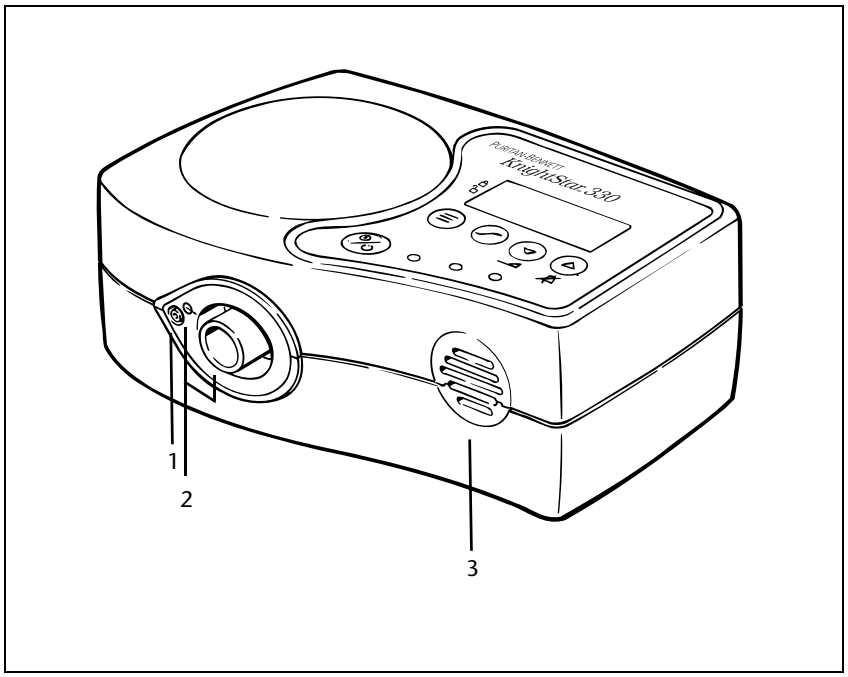


Figure 1-4. *KnightStar 330* front view

Table 1-9: *KnightStar 330* front view

Index (Figure 1-4 on page 1-18)	Labeling	Function
1	N/A	Patient pressure connector.
2		Air outlet connector.
3	N/A	Alarm speaker.

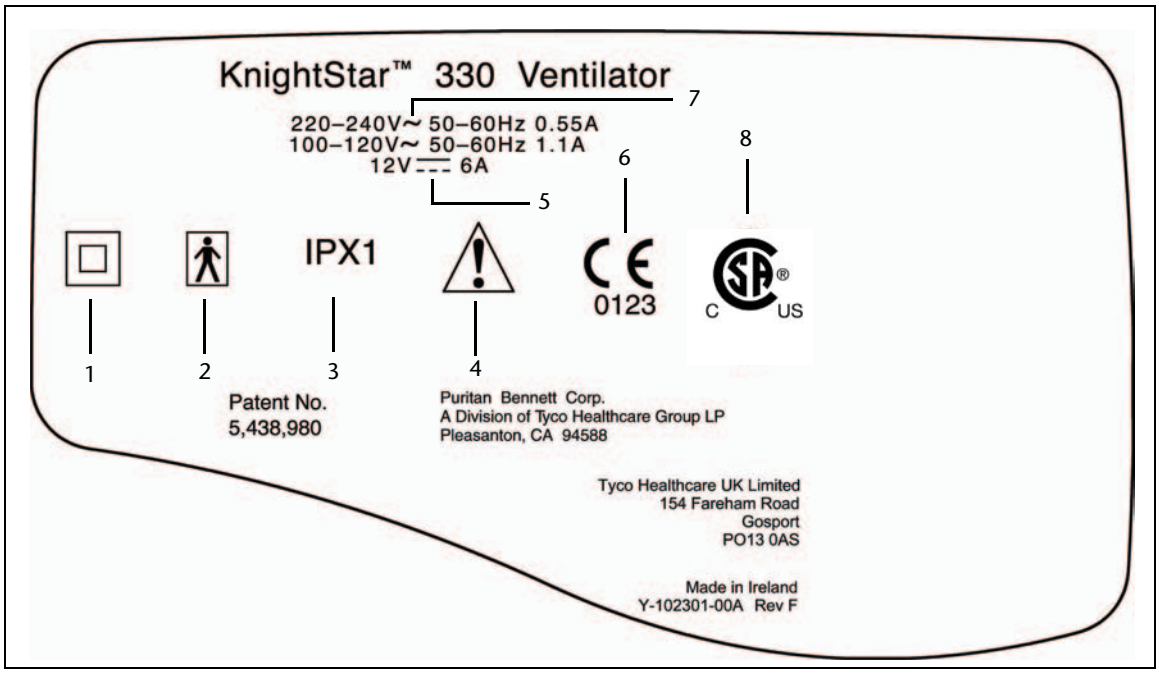


Figure 1-5. *KnightStar 330* bottom panel (International version shown)

Table 1-10: Symbols found on the *KnightStar 330* bottom panel

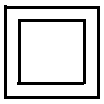
Item	Labeling	Description
1		Class II equipment (Per IEC 60601-1: Equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.)
2		Type BF equipment.
3	IPX1	Drip proof.
4		Attention! Consult accompanying documents.
5		Direct current (battery power).

Table 1-10: Symbols found on the *KnightStar 330* bottom panel (continued)

Item	Labeling	Description
6	CE 0123	This device complies with the requirements of Medical Device Directive 93/42/EEC concerning medical devices.
7		Alternating current (Mains/AC power from wall outlet).
8		Authorized to bear the CSA certification mark, signifying the product has been evaluated to the applicable CSA standards for use in the US and Canada. UL2601-1 CAN/CSA C22.2 No. 601.1- M90

1.13 Onscreen symbols and abbreviations

Table 1-11 lists the symbols that appear on the *KnightStar 330* display during operation.

Table 1-11: Display symbols

Symbol (Int'l)	Description	Symbol (North America)
START-UP DISPLAY SYMBOLS		
⧖	Total hours of operation	ON TIME
🚶 ⧖	Total compliance time (usage in hours)	USAGE
SN	Serial number	SN
🚶	Patient identification number (12 digits)	ID
MODES		
A/C	Assist control mode	A/C
CPAP	Continuous Positive Airway Pressure mode and pressure setting	CPAP
I/E	Inspiratory/Expiratory PAP mode	I/E
MEASURED PARAMETERS		
f	Respiratory rate	f
P	Current pressure	P
Vt	Tidal Volume	Vt
L	Leak rate	L
V̇	Peak inhalation flow	V̇
I:E	Ratio of inspiration time to expiration time (also a setting in A/C mode)	I:E
SETTINGS		
IPAP	Inspiratory pressure	IPAP
EPAP	Expiratory pressure	EPAP
f	Backup respiration rate (in A/C mode)	BACKUP f
ISENS	Inspiratory sensitivity	ISENS
ESENS	Expiratory sensitivity	ESENS
⤒ ⧖	Rise time setting	RISE
🔊 ⤒	Alarm volume level	🔊 ***VOL***
L ⤒	Leak alarm setting	***LEAK*** 🔊
P ⤓	Low pressure alarm setting	***LO P*** 🔊
P ⤒	High pressure alarm setting	***HI P*** 🔊
— ⧖	Delay time	DELAY

Table 1-11: Display symbols (continued)

Symbol (Int'l)	Description	Symbol (North America)
◢ ⧖	Ramp duration	RAMP
◢ *P*	Ramp start pressure	STRT P
L ⤒ ⤓	Interface (mask) leak/type (1-6)	MASK L
ALARMS		
🔊>*P* ⤒	High pressure alarm condition	🔊>*P* ⤒
🔊> *P* ⤓	Low pressure alarm condition	🔊> *P* ⤓
🔊:*L* ⤒	Leak alarm condition	🔊:*L* ⤒
f ⤓	Backup respiratory rate active (apnea)	*f* ⤓
🔊> # #	Malfunction (one or two digit error code, ##, denotes alarm type)	🔊> # #
STATUS		
— ◢	Ramp delay active	— ◢
🔒←	Lockout mode active	🔒←
🔓←	Lockout mode inactive	🔓←
🔊⊱	Alarm is silenced	🔊⊱

1.14 Ventilator serial numbers and software version

The *KnightStar 330* serial number and software version is displayed during the Power On Self Test (POST) that runs immediately after turning the ventilator on. The model number and serial number are also displayed on the bottom panel of the ventilator.

1.15 Tools, equipment, and service materials

The tools, equipment, and service materials listed in Table 1-12 are used to service the *KnightStar 330*.

Table 1-12: Tools, equipment, and service materials

Description	Manufacturer/model or Puritan Bennett part number	Where used
Calibration shell	S-231702-00B	Performance verification
6 ft. Patient circuit with pressure feedback	Y-261000-27	Performance verification
Calibrated manometer 0 to 50 cmH_2O range, minimum 0.5 cmH_2O resolution, or equivalent	Local supplier	Performance verification
60 cc syringe	Local supplier	Performance verification

Table 1-12: Tools, equipment, and service materials (continued)

Description	Manufacturer/model or Puritan Bennett part number	Where used
Outlet air filter	L-006197-000	Performance verification **NOTE:** Replace the outlet air filter at least once every 2 months.
KnightStar 330 Service Communications Cable	Y-103086-00A	Troubleshooting
24 V power supply	Local supplier	Troubleshooting
Static-dissipative field service kit (includes wrist strap, static dissipative mat, and earth (ground) cord)	4-018149-00	General repair
Anti-static adhesive tape	Local supplier	General repair
Disinfectant/cleaner	The following solutions are acceptable for disinfecting/cleaning the *KnightStar 330*: Mild detergent and water solution Isopropyl alcohol (70% solution) Bleach (10% solution) Glutaraldehyde (e.g. Cidex, 2.4% solution)	General cleaning
Paper towels or soft cloths	Local supplier	General cleaning
Tool kit, including the following: • Screwdriver, #1 Phillips • Screwdriver, #2 Phillips • Torx® T20 driver • Torque driver, #1 Phillips set to 5 ± 0.5 in-lb • Torque driver, Torx® T20 bit set to 15 ± 0.5 in-lb	Local supplier	General repair

1.16 Periodic maintenance

Caution

- To ensure proper operation, perform periodic maintenance and replace components at recommended intervals, as indicated in Table 1-13.

The *KnightStar 330* and associated test equipment require very little maintenance. Table 1-13 lists the periodic maintenance activities required for the *KnightStar 330*.

Table 1-13: Schedule of periodic maintenance

Frequency	Part	Maintenance
As Needed	Outer surfaces of the *KnightStar 330* ventilator	Clean surfaces with cloth dampened with warm soapy water or disinfectant described in Table 1-12. Wipe dry. Do not let liquid drip into any openings in the device.
Weekly	*KnightStar 330* air inlet filter (see Table 1-14 for ordering information)	Inspect filter. Replace if damaged. Use warm, soapy, sterile or distilled water to wash the filter. Rinse thoroughly with sterile or distilled water, and let air dry.
Every 2 months	Outlet air filter, *KnightStar 330* test setup (see Table 1-14 for ordering information)	Replace.

1.17 Spare parts

The *KnightStar 330* spare parts and their order numbers are listed in Table 1-14. Where applicable, item numbers from the assembly drawing in Figure 5-2 on page 5-3 are shown for reference. Parts may be ordered by calling Puritan Bennett at 1.800.635.5267.

Table 1-14: Spare parts list

Assembly Drawing Item No.	Description	Order No.
1	Base, enclosure	Y-101618-00A
27-28	Cover, enclosure with membrane switch (International)	Y-103027-00A
28	Switch, membrane (International) Switch, membrane (North America)	Y-101614-00A Y-103115-00A
30	Screws, 4-20 x 0.375, PH, Pan head	S-815371-00A
17	Filter, air inlet	Y-101922-00A
26	LCD display, 16 x 24	Y-102328-00A
25	Insulator, LCD	Y-102837-00A
15	Screw, Torx, hilo 2.2	Y-103095-000
19	Assembly, cooling fan	Y-103026-00
18	Adhesive foam, fan base	Y-102499-00A
20	Assembly, PCB, Alarm board	066035

Table 1-14: Spare parts list (continued)

Assembly Drawing Item No.	Description	Order No.
34	Shield, alarm	Y-102973-00A
N/A	Outlet air filter	L-006197-000
N/A	*KnightStar 330* Power cord, NEMA 1-15	Y-500012-00
N/A	*KnightStar 330* Power cord, CEE 7/16	Y-500013-00
N/A	*KnightStar 330* Power cord, UK	Y-500014-00

1.18 Service philosophy

Field service of the ventilator is limited to the service activities described in this manual. Any ventilator requiring replacement of the main PCBA, blower, and/or pitot tube should be sent to a Puritan Bennett Factory Service Center for repair. For field service, technical support, or technical information regarding the use of the serial communication functions, call Puritan Bennett Technical Support at 1.800.255.6774 (within the USA) or contact your Puritan Bennett representative (outside the USA).

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SECTION 2

Theory of operation

This section details the operational theory of the *KnightStar 330* and contains the following information:

- description of ventilator components
- overview of ventilator operation
- information on breath delivery and detection
- description of safety features

2.1 Ventilator components

The following components make up the *KnightStar 330* system:

- *KnightStar 330* bi-level ventilator
- Patient circuit with proximal pressure line
- Power cord
- Spare inlet air filter
- Outlet air/bacteria filter
- *KnightStar 330* Clinician's and User's Manuals

Puritan Bennett recommends using the *KnightStar 330* with 1.8 m (6 ft) or 2.4 m (8 ft) circuit and any of the following Puritan Bennett interfaces:

- *Breeze*™ Sleepgear with Dreamseal or Nasal Pillows
- *ADAM*™ Interface System
- SoftFit® Mask System and Ultra Nasal CPAP Mask

Figure 2-1 shows the *KnightStar 330* and its components.

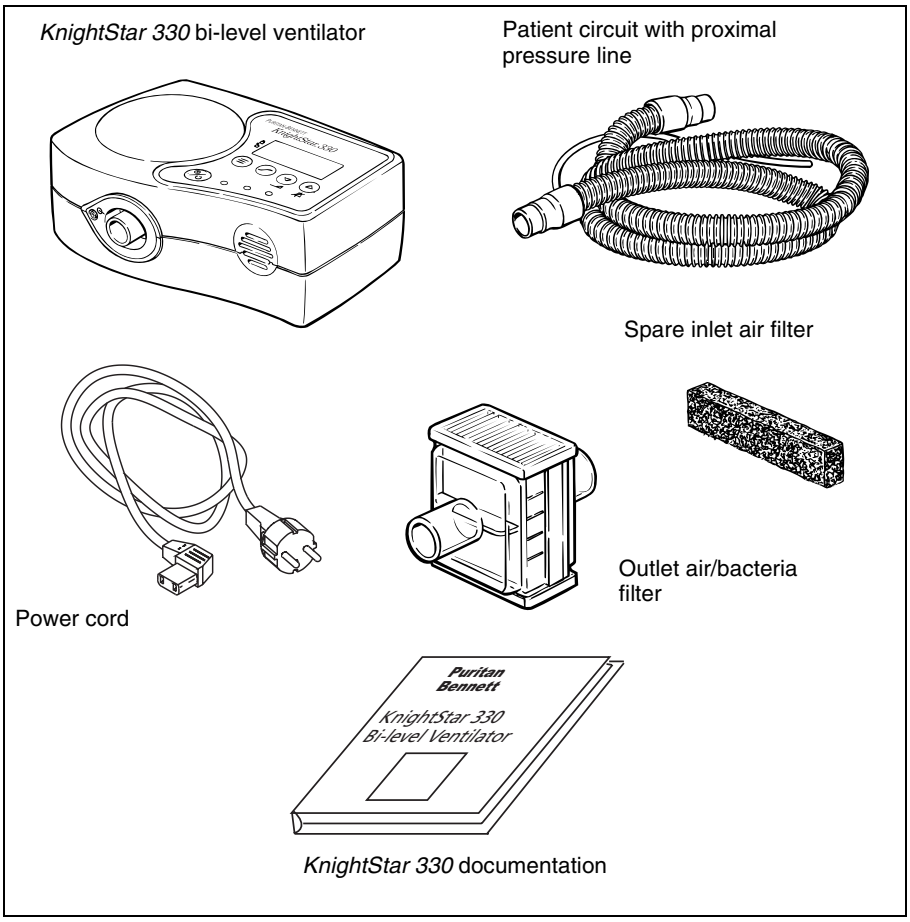

Figure 2-1. *KnightStar 330* Ventilator System

2.2 Operational overview

The *KnightStar 330* uses a micro-controller to control a 2-pole, 3-phase high frequency blower. The device can be operated using either AC or DC power per the specifications in Section 1.8

Ventilator breathing modes and settings are selected using the keypad and LCD on the top panel of the ventilator.

NOTE: If you would like to use the *KnightStar 330* in a special application that requires changing the settings via the RS-232 serial communications port, contact Puritan Bennett Technical Support at 1.800.255.6774 or your local Puritan Bennett representative for more information.

Once the settings are entered, the *KnightStar 330* can be put into Lockout mode, preventing accidental or unauthorized changes to prescribed settings. In Lockout mode, the user may only change the ramp duration, delay period prior to the start of ramp, and the ramp start pressure.

A gross particulate filter provided at the air inlet filters the incoming air. A high efficiency bacteria filter at the air outlet is provided and recommended for optimal device performance. A patient circuit with proximal pressure tube provides air delivery to the patient and pressure feedback to the device.

2.2.1 Operating modes

The *KnightStar 330* operates in four distinct modes:

- Stand-by
- Power On
- Delay/Ramp
- Therapy

Stand-by

When the AC power cord (or battery cable, if running on DC power) is connected, the device enters Stand-by mode and illuminates the green LED. Although the LCD remains blank, the device performs a self-test to verify the integrity of the firmware, hardware, and stored data. These tests include the following:

- Embedded ROM checksum test
- RAM read/write test
- Manufacturing EEPROM checksum test
- Real time clock valid date and time test
- Alarm board processor RAM read/write test
- Stuck switch test

The *KnightStar 330* remains in Stand-by mode until the On/Off key is pressed to turn it on. When the device is running, it may be returned to Stand-by mode by pressing and holding the On/Off key for three seconds. The *KnightStar 330* retains all settings in memory during periods when it is turned off.

NOTE: The *KnightStar 330* consumes battery power in Stand-by mode when connected to an external battery. To conserve battery power, disconnect the *KnightStar 330* from the battery when not in use.

Power on

The device powers on by pressing the On/Off key, then displays copyright notice, company name, and firmware version. Each time the device is turned on, the device performs the following internal tests:

- Valid settings test and critical parameter checksum
- Alarm/battery voltage test
- LED test

After these tests are performed, the *KnightStar 330* transitions into Delay/Ramp mode (if active) or Therapy mode.

Delay/Ramp

Upon completion of the power on sequence, the device begins the delay/ramp function if a delay and/or ramp are set and the function is active, indicated by the ⎽◢ symbol in the display. The Delay/Ramp mode can be cancelled or restarted by pressing the Delay/Ramp key.

The delay/ramp feature allows the patient to fall asleep during the delay period prior to the ventilator starting to deliver air flow. The delay period can be set from 0 to 30 minutes. When the delay is activated, both inspiratory and expiratory pressures will decrease to the ramp start pressure. After the delay time has elapsed, pressure will increase to the prescription pressures over the set ramp duration period, and the ventilator will start Therapy mode.

Therapy

In Therapy mode, the *KnightStar 330* ventilates patients in one of three breathing modes set by the clinician. The next section describes each mode.

2.2.2 Breathing modes

The *KnightStar 330* can ventilate a patient with the following breathing modes:

- CPAP (Continuous Positive Airway Pressure)
- I/E PAP (Inspiratory/Expiratory Positive Airway Pressure)
- A/C (Assist with Control)

CPAP

In the CPAP mode, the system delivers a continuous positive regulated airway pressure throughout the breath cycle at the prescribed level. The normal operating range is 3 to 20 cmH_2O.

The *KnightStar 330* continuously monitors and displays pressure (P) and leak rate (L) in CPAP mode.

I/E PAP

I/E PAP mode provides two pressure levels; an inspiratory pressure level of 3 to 30 cmH_2O and an exhalation pressure level of 3 to 20 cmH_2O.

In I/E PAP mode, the *KnightStar 330* continuously monitors and displays breath rate (f), pressure (P), tidal volume (Vt), leak rate (L). Pressing the Up Arrow key (with no alarm conditions present) will display the current peak flow ($\dot{V}$), and I:E ratio (I:E) values for five seconds.

If no inspiration is detected while at the IPAP level for the average inspiration period plus five seconds, the device enters a DEFAULT condition. During the DEFAULT condition, the device cycles to the EPAP level and remains at this level until it detects an inspiration trigger. If an inspiration is not detected while at the EPAP level, the device remains at the EPAP level until an inspiration is detected. During the DEFAULT condition the rest of the displayed values become 0, except for the I:E ratio, which becomes 1:0.0.

Upon detecting an inspiration trigger, the device resumes normal I/E PAP mode operation supporting all detectable spontaneous breathing at the prescribed pressure levels.

A/C

The A/C mode provides the same inspiratory and expiratory pressure levels as I/E PAP mode and provides an additional backup breath rate feature (normal operating range of 3 to 30 breaths/min) and a settable I:E ratio (normal operating range of 1:1.0 to 1:4.0).

In A/C mode, the *KnightStar 330* continuously monitors and displays breath rate (f), pressure (P), tidal volume (Vt), leak rate (L). Pressing the Up Arrow key (with no alarm conditions present) will display the current peak flow ($\dot{V}$), and I:E ratio (I:E) values for five seconds.

If the device is unable to track breathing efforts, or the patient's spontaneous respiratory rate falls to or below the prescribed backup breath rate, the device enters a DEFAULT condition and will cycle at the prescribed IPAP and EPAP levels, backup respiratory rate, and I:E ratio. If the backup rate cycles for five (5) continuous breaths, the ***f*** ↓ symbol will appear at the lower left corner of the display, and the yellow LED will illuminate (indicating a low priority alarm). The ***f*** ↓ symbol and yellow LED will remain active until the patient breathes on his or her own. When the back up rate is cycling, the patient data for "f" and I:E ratio are displayed as the prescribed values.

When the patient's spontaneous respiratory rate returns to a rate higher than the prescribed respiratory rate, the device will resume tracking the patient's spontaneous respiratory rate and will continue to provide pressure at the prescribed IPAP and EPAP levels.

2.3 Breath delivery

Control of delivered pressure is accomplished by measuring the pressure at the interface (mask) via a pressure measurement tube and sensor, and increasing or decreasing pressure by changing the motor speed with the motor/stator directly controlled by the micro-controller. A low-mass impeller allows for rapid speed (pressure) changes. This control method provides the ability to compensate pressure due to leaks in the patient circuit and changes in altitude. The micro-controller also monitors the analog flow and breath trigger signals to determine tidal volume and leak. Altitude compensation of the flow is accomplished by using an internal barometer that adjusts the flow value in software. Figure 2-2 shows a system block diagram with the micro-controller inputs and outputs that control breath delivery.

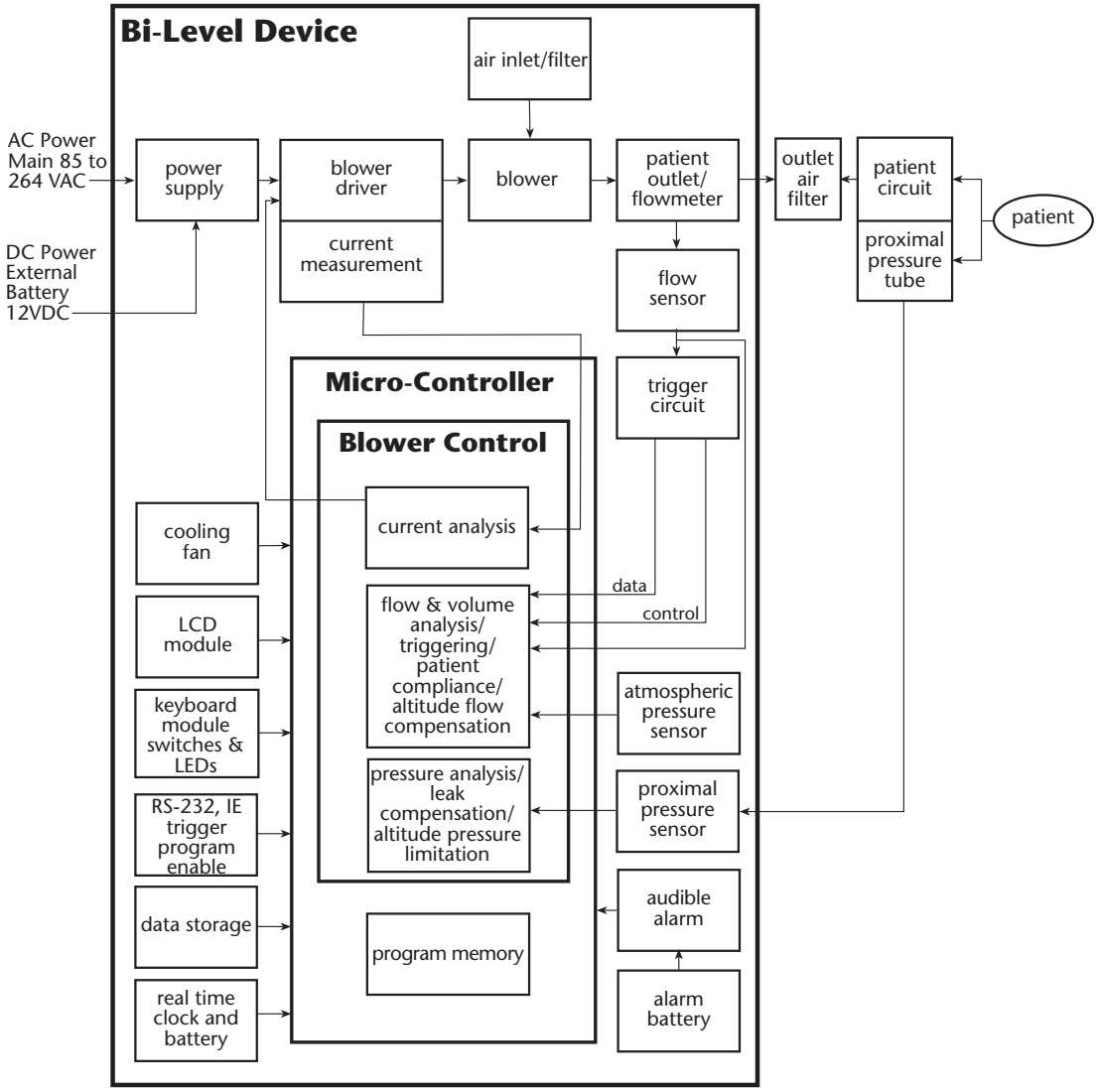

Figure 2-2. System and micro-controller block diagram

2.4 Breath detection

When in I/E PAP and A/C modes, the *KnightStar 330* monitors the flow to determine if the patient is inhaling or exhaling. Breath detection is performed using a mass flow sensor connected to a pitot tube at the blower outlet. The sensor output is then connected to an analog hardware circuit that sends inhale and exhale triggers to the micro-controller. An inhalation trigger occurs when the flow exceeds a fixed threshold set by the inspiration sensitivity. An exhalation trigger occurs when the difference between the instantaneous flow and the flow from an earlier time is less than the threshold set by the expiratory sensitivity. When the *KnightStar 330* changes from inhalation to exhalation or exhalation to inhalation, additional flow triggers are ignored for a 340 millisecond time period in order to prevent autocycling.

NOTE: Autocycling refers to a delivered breath that was not initiated by the patient.

The sensitivity of the breath detection set by the user is adjusted by the micro-controller. Five settings each for expiratory and inspiratory sensitivity are provided for clinician selection.

2.4.1 Expiratory sensitivity

Of the five levels of expiratory sensitivity available to the clinician, a setting of 1 causes the *KnightStar 330* to cycle into the expiratory phase quickly, and a setting of 5 allows the inspiratory flow to diminish significantly before cycling into the expiratory phase. Expiratory sensitivity is set via a digital potentiometer that controls the gain of a signal into an analog comparator circuit.

The exhalation detection is determined by comparing the high pass (0.015 Hz) and low pass (7.2 Hz) filtered flow signal with a delayed copy of itself (a 0.93 Hz low pass filter determines the delay). During an inhalation, the flow signal is more positive than the delayed signal; but when the flow signal diminishes to a value less than the delayed signal, exhalation is triggered. The amplitude of the delayed signal, which is determined by the gain setting in series with the 0.93 Hz filter, sets the threshold.

Figure 2-3 illustrates the effects of changing the expiratory sensitivity on the *KnightStar 330*. The longer it takes for the device to cycle into the expiratory phase, the greater the potential tidal volume delivered to the patient.

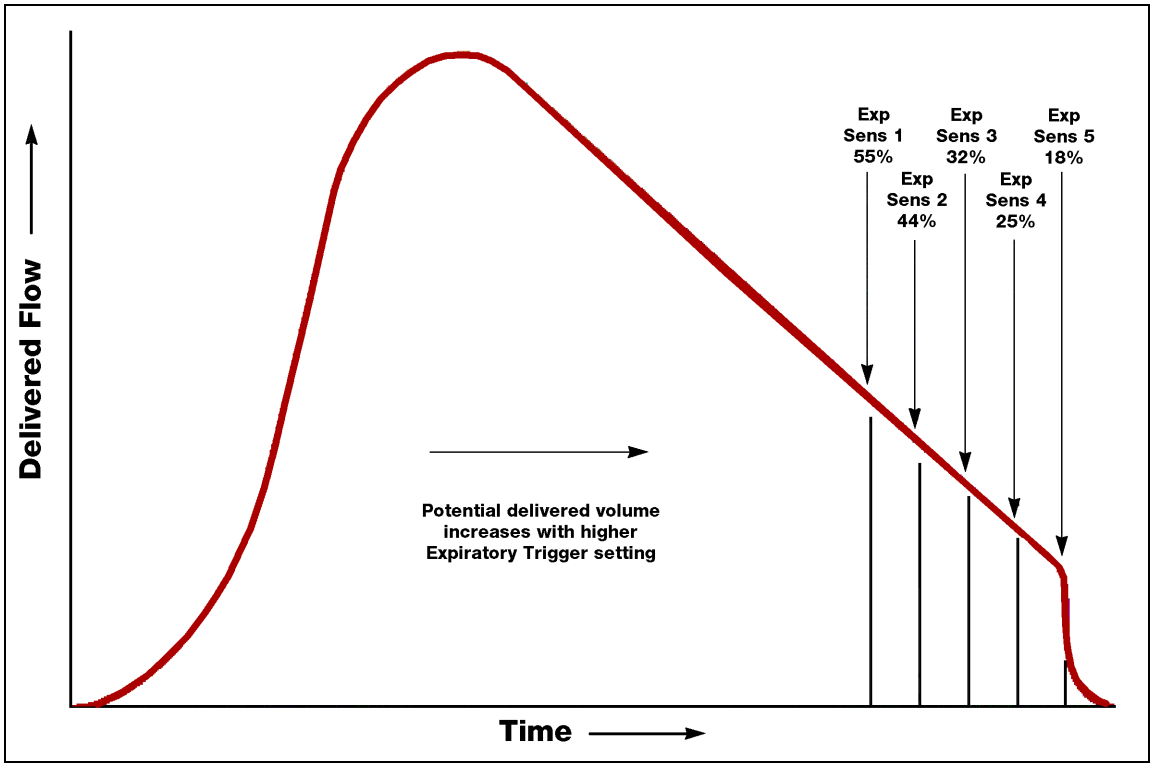

Figure 2-3. Effects of changing expiratory sensitivity

2.4.2 Inspiratory sensitivity

The inspiratory sensitivity is set by a DC voltage derived from a pulse width modulated (PWM) signal generated by the microcontroller and is partially affected by the signal from the exhalation stage. An inspiratory sensitivity setting of 1 is the most sensitive inhalation trigger, and a setting of 5 is the least sensitive. An inspiratory sensitivity adjusted too low may result in autocycling.

The inhalation detection is determined by comparing the high pass (0.015 Hz) and low pass (7.2 Hz) filtered flow signal to the delayed signal (from the 0.93 Hz filter) and to a fixed inhalation threshold. If the delayed signal is greater than the fixed threshold, the inhalation detection works as just the reverse of the exhalation threshold, triggering an inhalation when the filtered flow signal goes more positive than the delayed signal. If the delayed signal is less than the fixed threshold, the flow signal is compared to the fixed threshold.

2.4.3 Rise time

Rise time is the amount of time it takes for the inspiration to reach the set inspiratory pressure. Five rise time settings are available to the clinician. Figure 2-4 illustrates the relative time to reach a peak pressure level for rise time settings of 1, 3, and 5. The clinician adjusts the rise time setting based upon the patient's inspiratory demands and level of comfort. A lower rise time setting will enable the target pressure to be reached sooner than a higher rise time setting.

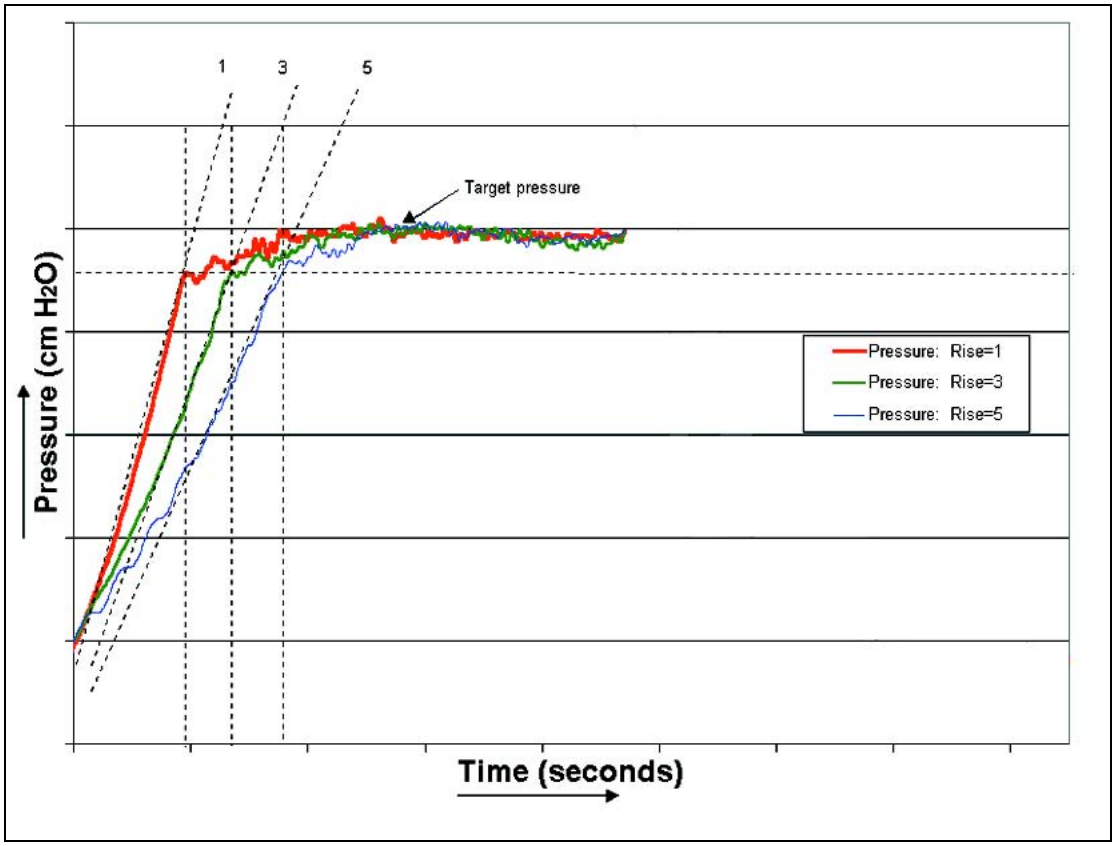

Figure 2-4. Rise Time

2.5 External battery operation

The *KnightStar 330* may be powered by either of two Puritan Bennett-supplied external 12 V DC batteries using a battery adapter cable, or by a standard 12V DC automobile battery using the appropriate cigarette lighter adapter cable. Table 1-1 on page 1-5 lists the ordering information for these parts.

Caution

Connect the *KnightStar 330* to only one power source at a time; external battery power or AC power. Damage to the device can result if connected to both power sources simultaneously.

When operating on battery power, the *KnightStar 330* functions as it does on AC power. The available 32 ampere-hour battery provides the *KnightStar 330* with up to 8 hours of operation, while the 7 ampere-hour battery powers the device for up to 3 hours.

To switch the *KnightStar 330* from Mains/AC power to battery power:

1. Turn the *KnightStar 330* off and unplug it from the AC power outlet.
2. Connect the appropriate cable to the battery and to the DC connector at the rear of the *KnightStar 330*.
3. Turn the *KnightStar 330* back on.

NOTE: The *KnightStar 330* consumes battery power in Stand-by mode when connected to an external battery. To conserve battery power, disconnect the *KnightStar 330* from the battery when not in use.

To switch the *KnightStar 330* from battery power to Mains/AC power:

1. Turn the *KnightStar 330* off and disconnect the battery cable from the device.
2. Connect the AC power cord to the rear of the *KnightStar 330* and to the Mains/AC outlet.
3. Turn the *KnightStar 330* back on.

2.6 Safety features

Several features have been designed into the *KnightStar 330* to protect the patient and user from injury following a single fault condition.

2.6.1 Overcurrent protection

Fuses in the Mains/AC inlet lines protect against electrical shock.

2.6.2 Controls protection

The Lockout mode allows the clinician to limit patient access to settings except for comfort features (delay time, ramp duration, and start pressure).

2.6.3 Power off protection

The On/Off key must be depressed for three seconds to turn off the device.

2.6.4 Maximum pressure

A software control shuts down the blower if delivered pressure exceeds 40 cmH_2O.

2.6.5 Audible alarms

The *KnightStar 330* includes an audible alarm capable of an adjustable sound level and can produce 85 dB(A) sound pressure level at a distance of one meter. An alarm sounds for various equipment fault conditions and device output conditions which exceed thresholds set by the clinician. Alarms are categorized into High, Medium, and Low priority.

2.6.5.1 High priority alarm

High priority alarms are indicated by a **flashing** red LED accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds).

High priority device alarms include:

- Low pressure
- Leak
- Loss of power
- Internal malfunction

2.6.5.2 Medium priority alarm

A medium priority alarm is indicated by a **flashing** yellow LED accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds).

Medium priority device alarms include:

- High pressure

2.6.5.3 Low priority alarm

Low priority alarms are indicated by a **steadily illuminated** yellow LED and no audible alarm.

Low priority device alarms include:

- Apnea

Table 4-1 on page 4-2 describes the various alarm conditions, how they are displayed on the LCD panel, and how to reset them.

2.6.5.4 Alarm control

The audible alarm function is provided on a separate alarm PCBA, which connects to the main PCBA via a 10-pin double row header. Table 2-1 lists the pin number and corresponding signal.

Table 2-1: Alarm connector pin-out

Pin No.	Signal
1	Ground
2	SDA signal of I2C interface
3	SCL signal of I2C interface
4	Red LED (on membrane switch) anode
5	Resistor and base of PNP transistor on main board that drives yellow LED
6	Ground
7	Alarm silence key input
8	+27 V from main board
9	Ground connection on main board for alarm board batteries
10	Ground

The alarm processor takes commands from the main PCBA processor via the I2C interface for the alarm controls (including sound level). The alarm processor can control its onboard audible alarm and the red and yellow LEDs on the membrane keypad. It is powered at maximum volume on the alarm PCBA with +13.5 V nominal with a 5 mA current limit. The alarm is equipped with a lithium battery power source. This allows the alarm to function during power outages or failure of the main PCBA.

SECTION 3

Performance verification

This section describes how to set up the *KnightStar 330* and verify the performance of the ventilator.

3.1 Initial ventilator cleaning and inspection

Prior to verifying the performance of the *KnightStar 330* it is important that the ventilator is clean and that the accessories are in good condition.

Warning

To prevent disease transmission, use personal protective equipment when handling contaminated bacterial filters or other patient accessories.

Caution

Do not soak any portion of the *KnightStar 330* in solvent, alcohol, or any other cleaning agent. Soaking ventilator components may damage the ventilator.

Clean and inspect the ventilator as follows:

1. Clean ventilator exterior using an approved cleaner/disinfectant. (See Table 1-12: Tools, equipment, and service materials on page 1-22.) After cleaning, ensure that there is no liquid residue at any of the ventilator openings or enclosure joints.
2. Refer to the assembly drawing shown in Figure 5-2, and Table 5-1 on page 5-3 for ITEM numbers called out in this step.

   Inspect the air inlet filter. To remove the air inlet filter, pull the baffle, ITEM 16, away from the ventilator and remove the foam filter, ITEM 17. Clean or replace as required. (See Table 1-13: Schedule of periodic maintenance on page 1-24 for air inlet filter cleaning instructions.) Re-install the baffle over the foam filter by snapping it into the base.
3. Visually inspect ventilator exterior for obvious problems such as missing, broken, or loose parts. Check the power cord for evidence of wear or damage. Repair or replace as needed.

3.2 System set-up

The following items are required for Performance Verification (see Table 1-12 on page 1-22 for part numbers):

- Calibration shell with included pressure tubing
- Patient circuit with pressure feedback
- Outlet air filter
- 60 cc syringe
- Calibrated manometer

Test set-up:

1. Set the *KnightStar 330* on the test bench, ensuring that it is placed such that there is at least 2.5 cm (1 in) of clearance at the back of the device.
2. Connect one end of the AC power cord into the rear panel of the *KnightStar 330*, and the other end into an AC wall outlet.
3. Attach the patient circuit and outlet air filter to the air outlet.
4. Attach the proximal pressure line to the patient pressure connector on the ventilator.

Refer to Figure 3-1 for connecting the ventilator components.

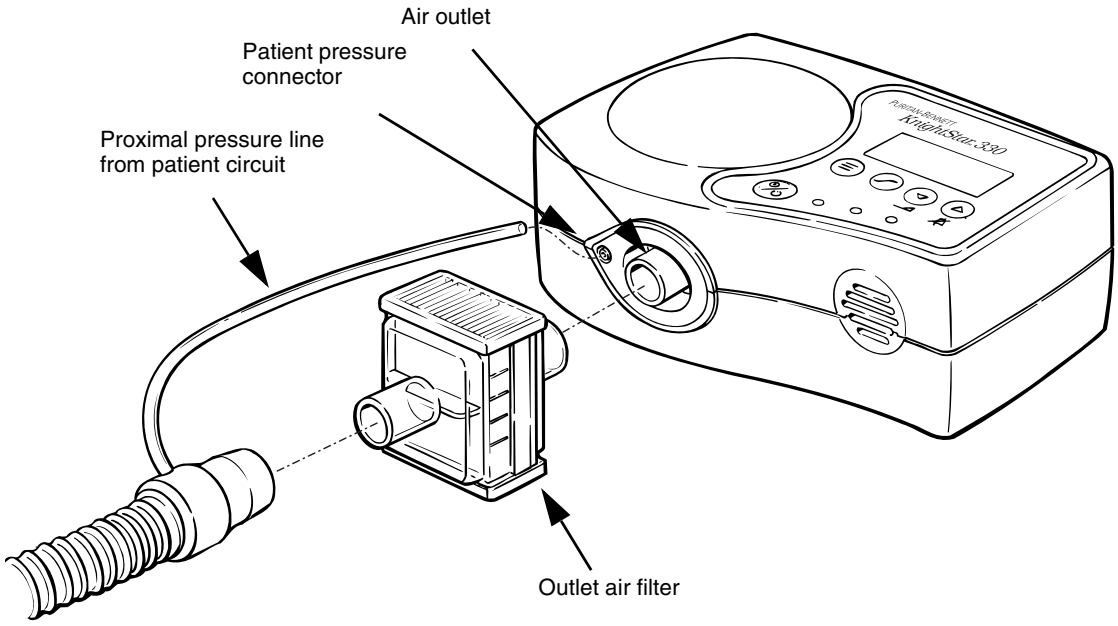

Figure 3-1. Connecting *KnightStar 330* components

5. Attach calibration shell to the patient circuit and connect the pressure tube between the manometer and calibration shell pressure ports. See Figure 3-2.

Figure 3-2. *KnightStar 330* test set-up

3.3 Performance verification tests

3.3.1 Functional performance tests

Warning

Be careful when handling the *KnightStar 330* during or immediately after use. Under specified conditions, some surfaces may become hot to the touch. This is a normal occurrence and is typical of this type of device.

NOTES:

- Because the *KnightStar 330* is double-insulated and has a non-grounded AC power connector, it is not necessary to perform hi-pot, ground continuity, or leakage current tests.
- If locked, unlock the *KnightStar 330* by simultaneously pressing and holding the Mode and Up Arrow keys for approximately 2 seconds. Verify that the indicator arrow on the LCD panel has moved from the locked to the unlocked position.

For the following Performance Verification tests:

- Perform the functional performance tests in the order that they appear.
- Change the breathing mode by repeatedly pressing the Mode key until the desired mode is displayed on the LCD panel.
- Change a specific setting by pressing the Settings key to scroll to the desired setting, then using the Up or Down Arrow keys to adjust the value. Exit the Settings mode by pressing the Mode key.
- Record the test results on the Performance Verification checklist found in Section 3.4.

3.3.1.1 Self tests

A self test is performed when the *KnightStar 330* is plugged into an AC wall outlet that verifies the integrity of the firmware, hardware, and stored data. See Section 2.2.1 for information on the specific self tests.

A Power On Self Test (POST) automatically runs each time the *KnightStar 330* is turned on. After pressing the On/Off key, the ventilator performs a test for valid settings, checksum verification, and battery, alarm, and LED tests, all of which take approximately 9 seconds. During POST, the ventilator displays the copyright notice, manufacturer's name, firmware version, checksum, alarm version, total hours of operation, total compliance time (patient usage) in hours, serial number, and patient ID number (if previously entered).

3.3.1.2 Blower test

Test the *KnightStar 330* blower as follows:

1. Turn the device on.
2. Select the CPAP mode.
3. Set the delay time [⧖ (International versions) or DELAY (North American version)] to 0 minutes.
4. Set the CPAP pressure to 3 cmH_2O. Note the sound of the blower at this setting.

5 Press and hold the Up Arrow key to scroll the CPAP pressure to 20 cmH_2O. Verify that the blower speed increases as the pressure setting increases.

6 Press and hold the Down Arrow key to return the CPAP pressure to 3 cmH_2O. Verify that the blower speed decreases as the pressure setting decreases.

3.3.1.3 Leak alarm test

To verify the proper function of the leak alarm:

1 Set the alarm volume, (or ***VOL***), to level 1.

2 Set the Leak alarm (***L*** or ***LEAK***) to 100 LPM.

3 Exit the settings mode.

4 Turn the *KnightStar 330* off by pressing and holding the On/Off key for 3 seconds. Wait for the motor to stop rotating.

5 Remove the calibration shell.

6 Turn on the *KnightStar 330* and let it run for approximately 3 minutes. Verify that the audible alarm activates, the red LED flashes, and the LEAK alarm indicator ***L*** appears at the lower left corner of the LCD panel.

7 Turn off the *KnightStar 330*.

3.3.1.4 Sensitivity test

Perform the following steps to ensure that the inspiratory and expiratory sensitivity settings function properly:

1 Attach the calibration shell to the patient circuit.

2 If it is not already connected, connect the tubing from the calibration shell to the manometer.

3 Turn on the *KnightStar 330*.

4 Select the I/E Mode.

5 Set the following parameters:
IPAP: 20 cmH_2O
EPAP: 10 cmH_2O
ISENS: 1
ESENS: 1
Low pressure alarm: 0
High pressure alarm: 0

6 Exit the Settings mode. Verify that the *KnightStar 330* begins to cycle between IPAP (20 cmH_2O) and EPAP (10 cmH_2O).

7 Increase ESENS to 5 and exit Settings mode. Verify that the *KnightStar 330* cycles at a slower rate.

8 Increase ISENS to 5 and exit Settings mode. Verify that the *KnightStar 330* does not cycle to IPAP and remains at the EPAP pressure (10 cmH_2O).

9 Reset ISENS and ESENS to 1 and exit Settings mode.

3.3.1.5 Pressure test

The following test ensures that the *KnightStar 330* is delivering the correct IPAP and EPAP pressures:

NOTE: To ensure accurate readings for the following pressure tests, verify that the manometer has been calibrated in accordance with the manufacturer's recommendation.

1. With the *KnightStar 330* still running at the settings from the sensitivity test, observe the pressure readings on the manometer. The output pressure should be within 1 cmH_2O for IPAP and EPAP settings.
2. Change the IPAP and EPAP settings to 17 and 7, respectively, and exit settings mode. Observe the output pressures and verify that they are within 1 cmH_2O of the IPAP and EPAP settings.

NOTE: At the pressure settings required in steps 2 and 3, it may be necessary to block the bleed hole in the calibration shell with your thumb for approximately 2 seconds to cause the *KnightStar 330* to deliver a breath.

3. Change the IPAP and EPAP settings to 14 and 4, respectively, and exit settings mode. Observe the output pressures and verify that they are within 1 cmH_2O of the IPAP and EPAP settings.
4. Reset IPAP and EPAP pressures back to 20 and 10 cmH_2O, respectively, and exit settings mode.

3.3.1.6 Delay sequence test

To ensure that the delay sequence functions properly:

1. Set the Delay time to 5 minutes.
2. Set the ramp duration (◢ ⧖ or RAMP) to 5 minutes.
3. Set the start pressure (◢ *P* or STRT P) to 4 cmH_2O.
4. Exit the Settings mode.
5. Press the Delay/Ramp key (Down Arrow) to start the delay. Verify that the delay symbol ⎯ ◢ appears on the LCD display.
6. Verify that the start pressure has dropped to 4 cmH_2O and that the ventilator starts operating when the delay time has elapsed.
7. Reset the delay time to 0.

3.3.1.7 Low pressure alarm test

To verify the low pressure alarm function:

1. Set the low pressure alarm to 11 cmH_2O.
2. Remove the calibration shell from the patient circuit.
3. Verify that the low pressure alarm sounds, the red LED flashes, and the low pressure alarm indicator (🔊 *P* ⬇) appears on the LCD panel.
4. Press the alarm silence key (Up Arrow) to mute the alarm.
5. Reconnect the calibration shell to the patient circuit. Verify that the alarm indicators (flashing red LED and LCD panel indicator) disappear, and the device returns to normal operation.

3.3.1.8 High pressure alarm test

The following test verifies the high pressure alarm function:

1. Set the following parameters:
   IPAP: 6 cmH_2O
   EPAP: 3 cmH_2O
   Low pressure alarm: 0 cmH_2O
   High pressure alarm: 7 cmH_2O
2. Exit settings mode and remove the calibration shell from the patient circuit.
3. Connect the syringe to the distal end of the patient pressure line and slowly push the entire 60 cc of air volume into the line. Verify that the pressure rises to 7 cmH_2O, the yellow LED flashes, the audible alarm sounds, and the high pressure alarm indicator appears on the LCD panel.
4. Remove the syringe and replace the calibration shell. Verify that the alarm indicators (flashing yellow LED and LCD panel indicator) disappear and the device returns to normal operation.

NOTE: If the syringe volume is delivered too quickly, an overpressure alarm condition can occur (internal malfunction error 55). If this alarm occurs, press the alarm silence key, disconnect the device from the power source for at least 30 seconds, then reconnect to power. Remove the syringe, reattach the calibration shell, and turn the device on. The device should operate normally.

3.3.1.9 Power failure indicator test

To test the power failure alarm function:

1. While the *KnightStar 330* is running, disconnect the Mains/AC power cord.
2. Verify that the audible alarm sounds and the red LED flashes. Press the Alarm Silence key to mute the alarm.
3. Reconnect the Mains/AC power cord. The device should enter Stand-by mode.

3.3.1.10 Autoclear procedure

To reset the *KnightStar 330* to its factory default settings and to clear patient settings and the compliance log flash memory, perform the autoclear procedure as follows:

With the *KnightStar 330* in stand-by mode:

1. Simultaneously press and release the On/Off, Mode, and Up Arrow keys. In approximately 20 seconds the *KnightStar 330* will power on, and perform a self test.
2. Verify that Xs appear in the patient ID field on the LCD display. The Xs indicate that the flash memory has been cleared.
3. Verify that the ventilator resumes ventilation in A/C mode at the initial factory settings. (See Table 1-6 on page 1-11.)
4. Turn the *KnightStar 330* off.

3.4 *KnightStar 330* performance verification checklist

Record performance verification test results on the following checklist:

Table 3-1: Performance verification checklist

KnightStar 330 Serial Number: _____		
Technician: _____ Date tested: _____		
Procedure	**Pass ✓**	**Fail ✓**
Initial Ventilator Cleaning and Inspection		
No fluid residue in or around ventilator openings and enclosure joints.	❒	❒
Inlet filter is clean and in place.	❒	❒
Inlet baffle is present.	❒	❒
No dents, scratches, loose parts or evidence of dropping or other abuse.	❒	❒
Mains/AC power cord in good condition.	❒	❒
Other observations:		
Functional Performance Tests		
Ventilator self test (Section 3.3.1.1)	❒	❒
Blower test (Section 3.3.1.2)	❒	❒
Leak alarm test (Section 3.3.1.3)	❒	❒
Sensitivity test (Section 3.3.1.4)	❒	❒
Pressure test (units in cmH_2O) (Section 3.3.1.5) IPAP setting Meas. IPAP press. EPAP setting Meas. EPAP press. 20 _____ 10 _____ 17 _____ 7 _____ 14 _____ 4 _____	 ❒ ❒ ❒	 ❒ ❒ ❒
Delay sequence test (Section 3.3.1.6)	❒	❒
Low pressure alarm test (Section 3.3.1.7)	❒	❒
High pressure alarm test (Section 3.3.1.8)	❒	❒
Power failure indicator test (Section 3.3.1.9)	❒	❒
Autoclear procedure (Section 3.3.1.10)	❒	❒

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SECTION 4

Troubleshooting

This section describes the actions necessary to diagnose and troubleshoot the *KnightStar 330*. It includes a list of alarm conditions, a table for solving problems based upon the most probable causes, and a table for interpreting individual internal malfunction error codes.

Prior to diagnosing the problem, verify the following:

- Power is securely connected to the *KnightStar 330*.
- Air outlet filter, patient circuit and proximal pressure tube are properly connected, calibration shell is properly attached (where required), and that these parts are not damaged, causing a system leak.

4.1 Alarms

An equipment malfunction or system error will cause the *KnightStar 330* to invoke one or more of the following responses:

- Illuminated or flashing yellow or red LED (indicates alarm priority)
- Audible alarm
- Displayed error code or alarm symbol

Alarms are classified by priority:

- HIGH priority—Indicated by a flashing RED LED accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds).
- MEDIUM priority—Indicated by a flashing YELLOW LED accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds).
- LOW priority—Indicated by a steadily illuminated YELLOW LED on the control panel and no audible alarm.

In many cases, the alarm condition can be remedied by patient or caregiver intervention.

Table 4-1 describes the alarm conditions.

NOTE: The Alarm Silence key (Up Arrow) may be pressed to mute the alarm for 1 minute.

Table 4-1: Alarm conditions

Alarm Type	Priority	Description	Display Panel Symbol and LED	Alarm Volume*	Reset Condition
Low pressure	High	Pressure at interface falls below low pressure alarm setting for 10 seconds. (Minimum alarm setting is 1 cmH_2O below prescribed IPAP setting.)	P ↓ Flashing **red** LED	Adjustable from 0 – 3: 0 = Off 3 = Loudest	Pressure rises above low pressure alarm setting.
Leak	High	Estimated leak rate rises above leak alarm setting for 60 seconds.	L ↑ Flashing **red** LED	Adjustable from 0 – 3: 0 = Off 3 = Loudest	Leak flow rate decreases to less than leak alarm setting. Eliminate leaks in ventilator system, patient mask or breathing circuit.
Power loss	High	Loss of Mains/AC or battery power.	Display is blank Flashing **red** LED	Always enabled; Alarm volume = 3	Press alarm silence key. Restore Mains/ AC or external battery power.
Internal Malfunction	High	Device detects an internal failure.	# # where ## represents a unique error code Flashing **red** LED	Always enabled; Alarm volume = 3	Disconnect the device from the power source for at least 30 seconds; then reconnect. See Table 4-3 for specific information.
High pressure	Medium	Pressure at interface rises above the high pressure alarm setting for 10 seconds. (Minimum alarm setting is 1 cmH_2O above prescribed IPAP setting.)	P ↑ Flashing **yellow** LED	Adjustable from 0 – 3: 0 = Off 3 = Loudest	Pressure decreases to less than high pressure alarm setting.
Apnea	Low	Patient's spontaneous respiratory rate remains at or below the prescribed respiratory rate for 5 breaths in A/C mode.	f ↓ **Yellow** LED steadily illuminated	No audible alarm present	Patient's breath rate returns to the prescribed rate.

* For Japanese versions of the *KnightStar 330*, alarm volume cannot be turned off. Adjustment range is 1(softest) to 3 (loudest).

4.2 Troubleshooting checklist

Use Table 4-2 to diagnose malfunctions of the *KnightStar 330*.

NOTE: Due to specific design interactions between the Main PCBA, blower, and pitot tube, individual field replacement of any of these parts is not possible. If required, please return the *KnightStar 330* to a Puritan Bennett factory service center for repair.

Table 4-2: Troubleshooting checklist

Observed Problem	Diagnostic Questions			Probable Cause	Action
No airflow out of device	Display turns on?	Motor turns on?			
	Yes	Yes		Obstructed air inlet	Check for proper air inlet clearance; check air inlet filter and clean or replace if necessary.
				Damaged blower	Return device to factory service center for repair.
	No	No		PCBA failure	
	Yes	No		Motor damaged	
Low airflow out of device	Restricted air inlet?	Device displays high pressure?			
	Yes	No		Obstructed air inlet	Check for proper air inlet clearance; check air inlet filter and clean or replace if necessary.
				Blower failure	Return device to factory service center for repair.
	No	No		Bellows slipped off	Return device to factory service center for repair.
	No	Yes		Pressure sensor failure	Return device to factory service center for repair.

Table 4-2: Troubleshooting checklist (continued)

Observed Problem	Diagnostic Questions			Probable Cause	Action
Power loss	Power cord OK?	Power source OK?			
	No	Yes		Power cord failure	Replace power cord.
	Yes	No		Inadequate input power source	Restore input power to specified input range (refer to Table 1-2 on page 1-5).
	Yes	Yes		Power supply failure	Return device to factory service center for repair.
Overpressure	Pressure tubes OK?	Error reoccurs after reset?			
	Yes	Yes		Pressure sensor failure	Return device to factory service center for repair.
High pressure	Pressure tubes OK?	Alarms set too low?			
	Yes	No		Pressure sensor failure	Return device to factory service center for repair.
Low pressure	Pressure tubes OK?	Blower problems?			
	Yes	No		Pressure sensor failure	Return device to factory service center for repair.
	No	No		Tube detached	Re-attach pressure tube (refer to Figure 5-8 on page 5-7 for tubing connections).
	Yes	Yes (excessive noise, scraping)		Broken impeller/motor failure	Return device to factory service center for repair.

Table 4-2: Troubleshooting checklist (continued)

Observed Problem	Diagnostic Questions			Probable Cause	Action
Circuit leak	Bellows OK?	Flow sensor tubes OK?			
	Yes	Yes		Flow sensor failure	Return device to factory service center for repair.
	No	Yes		Bellows failure	Return device to factory service center for repair.
	Yes	No		Tubes detached	Re-attach flow sensor tubes (refer to Figure 5-10 on page 5-8 for tubing connections).
Low breath rate (device not triggering)	Flow sensor tubes OK?	Bellows OK?	Pitot tube damaged?		
	No	Yes	No	Tubes detached	Re-attach flow sensor tubes (refer to Figure 5-10 on page 5-8 for tubing connections).
	Yes	Yes	No	Flow sensor failure	Return device to factory service center for repair.
				Inspiratory or expiratory sensitivity settings too high	Adjust inspiratory and/or expiratory sensitivity to lower settings.
	Yes	No	No	Bellows failure	Return device to factory service center for repair.
	Yes	Yes	Yes	Pitot tube failure	Return device to factory service center for repair.

Table 4-2: Troubleshooting checklist (continued)

Observed Problem	Diagnostic Questions			Probable Cause	Action
No display	LCD panel damaged?	LCD panel seated properly on Main PCBA?			
	No	No		Reassembled incorrectly	Fully seat LCD panel to main PCBA (refer to Section 5.6 on page 5-5).
				Improper input power	Ensure Mains/ AC power source is adequate or external battery is charged.
	Yes	Yes		Device dropped or excessive force applied to LCD panel	Replace LCD panel (refer to Section 5.6 on page 5-5).

4.3 Internal malfunction errors

Table 4-3 lists the internal malfunction errors for which there is a high priority alarm and a displayed error code, and the appropriate action to take to reset or repair the device.

Table 4-3: Internal malfunction error list

Internal Malfunction Error Code	Error Type	Condition occurs when:	Check for	Probable Cause	Action
1	ROM checksum	ROM checksum does not match internal checksum during POST		component failure	Return device to factory service center for repair.
2	Calibration checksum	Calculated checksum of manufacturing EEPROM does not match stored value		Manufacturing EEPROM failure	1. With the device powered off, apply 24V to pin 9 on RS-232 connector using KS 330 Service Communications Cable (refer to Table 1-12 on page 1-22 for cable part number). 2. Turn the device on, and let POST run until finished. 3. Turn the device off, and remove 24V. **Caution** Do not press any keys while 24 V is applied.
3	Settings checksum	Calculated checksum of settings EEPROM does not match stored value		Settings EEPROM failure	Perform the autoclear procedure (refer to Section 3.3.1.10 on page 3-6); then cycle power.
4	RAM error	Device writes pattern to RAM during POST and read pattern does not match		component failure	Return device to factory service center for repair.

Table 4-3: Internal malfunction error list (continued)

Internal Malfunction Error Code	Error Type	Condition occurs when:	Check for	Probable Cause	Action
5	Stack overflow	Software stack is overwritten		component failure	Return device to factory service center for repair.
7	Spurious interrupt	More than 2 undefined interrupts detected		component failure	Return device to factory service center for repair.
8	Stuck key	Device senses a continuous key press		Key pressed during POST or stuck key	1. Disconnect the device for at least 30 seconds; then reconnect to AC power. 2. Press the On/Off key once and ensure that NO keys are pressed during POST. 3. If the error persists, replace the membrane switch (refer to Section 5.5 on page 5-4).
9	Alarm test failure	Alarm processor read during POST and alarm test failure bit is set. This can occur when power is removed from the device during an alarm condition.		• Alarm battery voltage is below its low voltage threshold • 3400 Hz alarm mode output frequency can't be detected • Main power can't be detected	1. Disconnect the device for at least 30 seconds; then reconnect to AC power. 2. If the error persists, replace alarm PCBA (refer to Section 5.7 on page 5-5).
10	Persistent SPI read failure	SPI read returned non-ready status following a flash read operation during POST		Flash failure	Return device to factory service center for repair.
11	Persistent SPI write failure	SPI write returned non-ready status following a flash write operation during POST		Flash failure	Return device to factory service center for repair.

Table 4-3: Internal malfunction error list (continued)

Internal Malfunction Error Code	Error Type	Condition occurs when:	Check for	Probable Cause	Action
30	Synchronization loss	Device detects an overcurrent condition due to the loss of motor synchronization. Device attempts to restart the blower.	Blower wiring harness connector not seated properly in J3 connector on main PCBA	Damaged motor or motor connection	Re-seat blower harness connector. If problem persists, return device to factory service center for repair.
31	Invalid date/ time	Invalid date or time detected during POST		Invalid clock setting or clock failure	Return device to factory service center for repair.
32	Multiple watchdog	Watchdog reset occurs more than 3 times in 10 hours		component failure	Return device to factory service center for repair.
37	I2C error	I2C error bit is set		component failure	Return device to factory service center for repair.
38	Alarm board error	Settings error bit set when reading the alarm status register		Alarm board component failure	1. Disconnect the device for at least 30 seconds; then reconnect to AC power. 2. If error persists, replace Alarm PCBA (refer to Section 5.7 on page 5-5).
41	Call-out error (error code is displayed but no audible alarm sounds)	I2C read error during call-out sequence		component failure	Return device to factory service center for repair.
42	Pressure sensor error	Pressure sensor signal not present	Ventilator airway or patient circuit obstructions	Pressure sensor failure	Remove obstructions from ventilator airway or patient circuit. If problem persists, return device to factory service center for repair.
44	Max synchronization loss	More than 3 desyncs (error 30) in 30 seconds. Device attempts to restart the blower.	Blower wiring harness connector not seated properly in J3 connector on main PCBA	Motor or motor connection is damaged	Re-seat blower harness connector. If problem persists, return device to factory service center for repair.

Table 4-3: Internal malfunction error list (continued)

Internal Malfunction Error Code	Error Type	Condition occurs when:	Check for	Probable Cause	Action
45	Barometer error	Barometer stuck high or low when read		Barometer failure or incorrect transmit and receive connection on RS-232 port	Return device to factory service center for repair.
46	Flow sensor error	Flow sensor stuck high or low for 60 seconds		Flow sensor failure	Return device to factory service center for repair.
47	Blower frequency error	Blower frequency rails to high or low limit for 90 seconds during breath detection (4 breaths detected)	Good condition of pitot tube and proper connection of silicone tubing	Pressure sensor failure	Re-connect silicone tubing and verify good condition of pitot tube. If problem persists, return device to factory service center for repair.
55	Over-pressure	Pressure > 40 cmH_2O for at least 0.5 seconds	Full face mask being used	Patient cough into full face mask	Disconnect the device from the power source for at least 30 seconds; then reconnect. Turn the device on. Device resets if cause of overpressure condition is eliminated. Use Puritan Bennett-recommended patient interfaces.

4.4 Logged errors

Table 4-4 lists the errors that are logged in memory but may not annunciate an audible alarm, and the action to take to reset or repair the device.

Table 4-4: Logged errors

Error Code	Error Type	Condition occurs when:	Check for	Probable cause	Action
33	Compliance log full	A steadily illuminated yellow LED appears on the top panel with no indicator displayed on the LCD panel. When the compliance log is full, the device continuously overwrites all data after the first 72 hours.		Log full	Clear compliance log by performing the autoclear procedure (refer to Section 3.3.1.10 on page 3-6); then cycle power.
35	RS-232 command error	Device receives undefined command through its serial port	Appropriate @04 response being sent	External software code error	Contact Puritan Bennett Technical Support for more information.
36	RS-232 checksum error	Device receives a checksum that does not match the one calculated for the current message sent	Appropriate @E0 response being sent	External software code error	Contact Puritan Bennett Technical Support for more information.
40	Overvoltage	Motor voltage is greater than 31 V		Power supply failure or blown fuse (F2)	Return device to factory service center for repair.

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SECTION 5

Repair

This section provides repair information for the *KnightStar 330*. After diagnosing the problem using the Troubleshooting section, perform the suggested repair using the instructions in this section.

Warning

Disconnect power to the *KnightStar 330* before cleaning or repair. After performing repairs on the *KnightStar 330*, run the complete suite of Performance Verification tests contained in Section 3. This ensures proper performance of the ventilator prior to patient use.

5.1 Tools, test equipment, and service materials

Use the tools and test equipment listed in Table 1-12 on page 1-22 to repair the *KnightStar 330*.

Refer to Table 1-14 on page 1-24 for replacement part ordering information.

5.2 Ventilator cleaning and inspection

Warning

To prevent disease transmission, use personal protective equipment when handling contaminated bacterial filters or other patient accessories.

Caution

Do not soak any portion of the *KnightStar 330* in solvent, alcohol, or any other cleaning agent. Soaking ventilator components may damage the ventilator.

Clean and inspect the ventilator as follows:

1. Clean ventilator exterior using an approved cleaner/disinfectant. (See Table 1-12 on page 1-22.) After cleaning, ensure that there is no liquid residue at any of the ventilator openings or enclosure joints.
2. Inspect the air inlet filter. To remove the air inlet filter, pull the baffle, ITEM 16, away from the ventilator and remove the foam filter, ITEM 17. Clean or replace as required. (See Table 1-13 on page 1-24 for air inlet filter cleaning instructions.) Re-install the baffle over the foam filter by snapping it into the base.
3. Visually inspect ventilator exterior for obvious problems such as missing, broken, or loose parts. Repair as needed.

5.3 Ventilator assembly drawing

Prior to disassembling the *KnightStar 330*, familiarize yourself with the assembly drawing in Figure 5-2 and the items listed in Table 5-1. All repair instructions refer to the assembly drawing item numbers.

5.4 Initial ventilator disassembly

Caution

Before handling PCBAs with static-sensitive components inserted, prevent electrostatic discharge (ESD) damage by using the static-dissipative field service kit when disassembling the device. Place the strap connected to the static dissipative mat around your wrist before handling static-sensitive components, and use the static dissipative mat as the work surface.

Assemblies that are static sensitive may be handled without the technician being attached to the static-dissipative workstation ***only*** if the assemblies are placed into a protective container such as a conductive bag or case, or vendor packaging.

To open the *KnightStar 330*:

1. Turn the device upside down on work surface with base facing up.
2. Using a screwdriver with T-20 Torx® bit (or #2 Phillips for devices built prior to Oct. 2001), remove the four screws, ITEM 15, shown in Figure 5-1.

Figure 5-1. Removing the enclosure base screws

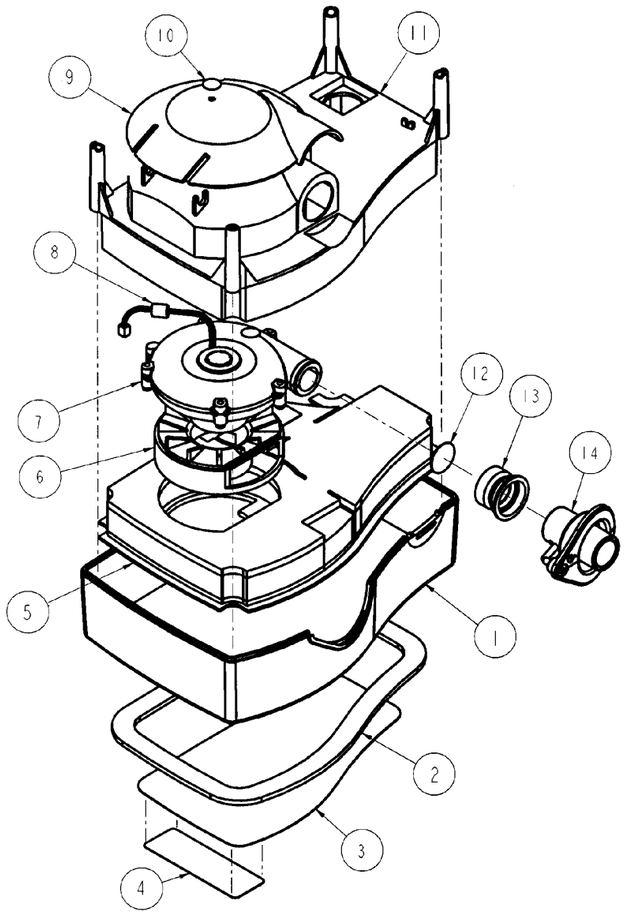
3. While holding both housing halves together, turn the device over and place it onto its base.
4. Carefully remove the enclosure cover, ITEM 27, by rotating it towards the back of the device, taking care while separating the tongue and groove section of the base, cover, and pitot tube (Figure 5-3).

Caution

Be careful not to damage the three electrical connectors on the back side of the device.

Table 5-1: *KnightStar 330* component descriptions

Item	Description
1	Base, enclosure
2	Foot, base, enclosure
3	Label, KS 330
4	Label, serial number
5	Case, foam
6	Suspension/muffler, blower
7	Blower assembly
8	Ferrite, clamp on
9	Dampener
10	Wire patch, dampener
11	Chassis, enclosure
12	Screen, blower housing
13	Bellows, blower housing
14	Tube, pitot
15	Screw, Torx, hilo 2.2 (4pl)
16	Baffle
17	Filter, air inlet
18	Adhesive foam, fan base
19	Assembly, cooling fan
20	Assembly, PCB alarm board
21	Tube, silicone, 10.0”
22	Tube, silicone, 4.25”
23	Tube, silicone, 1.25”
24	Spacer (2 pl)
25	Insulator, LCD
26	LCD display, 16x24
27	Cover, Enclosure
28	Switch, Membrane
29	Pad, foam, cover, interior
30	Screw, 4-20 x .375, PH. pan head (2 pl)
31	RS-232 PCBA
32	Insulator, RS-232 PCBA
33	Assembly, PCB, main board
34	Shield, alarm
35	Battery, coincell, lithium 3V



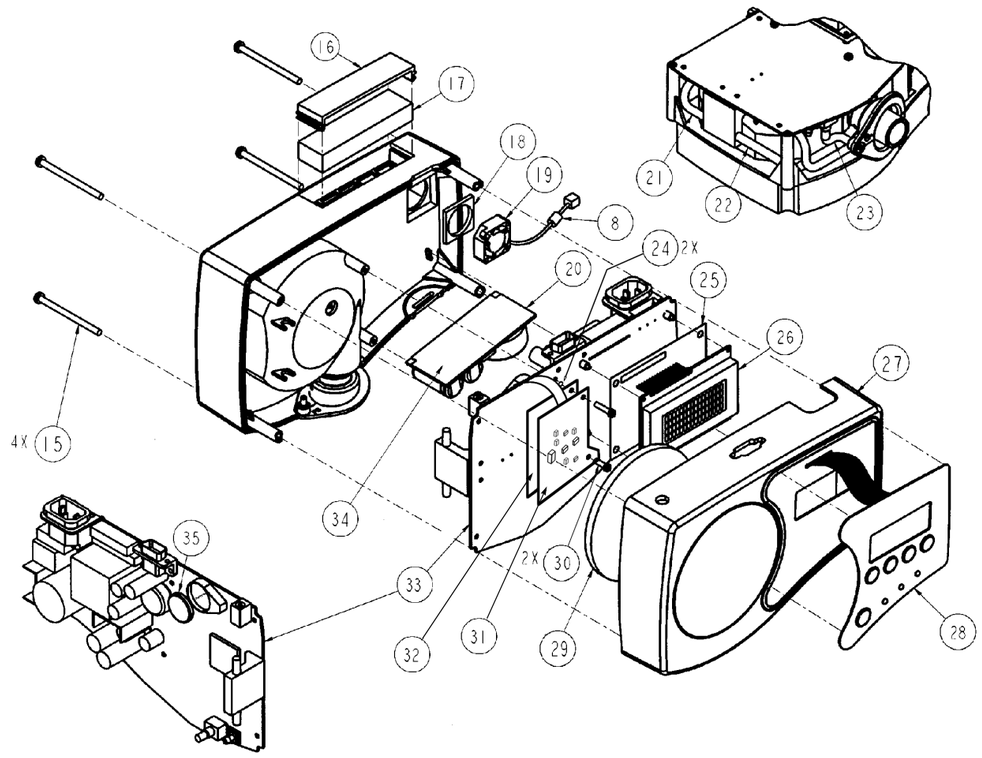


Figure 5-2: *KnightStar 330* assembly drawing

Figure 5-3. Removing the enclosure cover

5 Place the enclosure cover on the work surface at the back of the device and carefully disconnect the membrane switch ribbon cable connector from the J5 header on the Main PCBA (Figure 5-4).

Figure 5-4. Membrane switch ribbon cable

5.5 Membrane switch replacement

To replace the membrane switch:

1 Perform the ventilator disassembly steps in Section 5.4.

2 Remove the old membrane switch, ITEM 28, from the enclosure cover.

3 Clean the recessed area of the enclosure cover with isopropyl alcohol to remove old adhesive. Make sure the recessed area is dry before proceeding with the next step.

4 Peel the paper backing away from the new membrane switch and insert the ribbon cable through the slot in the top of the enclosure cover.

5 Carefully apply the membrane switch to the recessed area on the enclosure cover. Make sure that the membrane switch completely adheres to the cover.

6 Complete the assembly by performing the steps in Section 5.9.

5.6 LCD panel replacement

To replace the LCD panel:

1 Disassemble the ventilator according to the steps in Section 5.4.

2 At each corner of the LCD panel, ITEM 26, use needle nose pliers to pinch the end of the plastic stand-off used to secure the panel in place, and gently pull the corner over the stand-off.

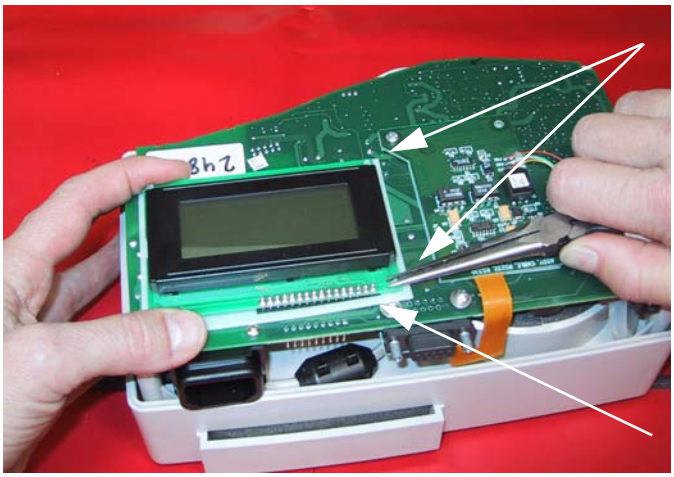


Figure 5-5. Removing the LCD panel

3 Carefully pull the LCD panel away from the J4 connector on the Main PCBA.

4 Remove the LCD panel insulator, ITEM 25, and discard if it is damaged. Install a new LCD panel insulator, if necessary.

5 Install the new LCD panel by aligning the header pins on the LCD panel with the J4 connector on the Main PCBA, and pressing the corners onto the standoffs. Make sure that the ends of the four standoffs fully engage into the holes on the LCD panel.

Caution

Be careful to align the header and connector properly.

Do not press directly on the LCD screen when installing the new LCD panel.

6 Remove the protective plastic film covering the LCD screen.

7 Complete the assembly by performing the steps in Section 5.9.

5.7 Alarm PCBA replacement

To replace the alarm PCBA:

1 Perform the ventilator disassembly steps in Section 5.4.

2 Gently lift the pitot tube, ITEM 14, out of its groove in the lower housing and slide it away from the bellows, ITEM 13. Be careful not to let the bellows pull away from the blower assembly, ITEM 7 (Figure 5-6). Do not disconnect any of the silicone tubing from the pitot tube, flow sensor, or pressure transducer.

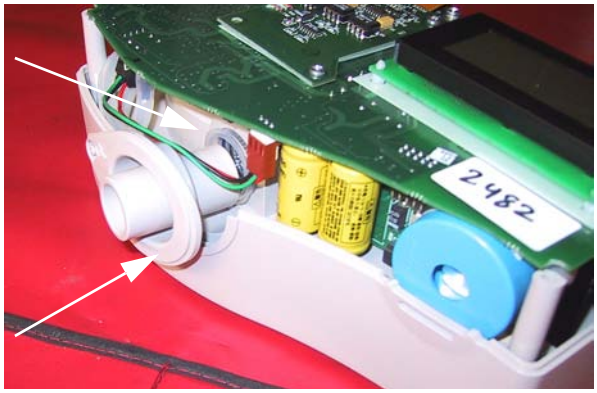


Figure 5-6. Removing pitot tube from enclosure groove and bellows

3 Remove the two screws, ITEM 30, using the #1 Phillips screwdriver (Figure 5-7). For assemblies with an RS-232 PCBA, ITEM 31, carefully remove the insulator, ITEM 32, and (if loose) the two plastic spacers, ITEM 24, from beneath the RS-232 PCBA mounted on the Main PCBA. Set these parts aside for re-assembly.

NOTE: Devices manufactured prior to 2004 do not have the RS-232 PCBA, insulator, and spacers.

Figure 5-7. Removing the Main PCBA screws

Caution

Be careful when handling the Main PCBA with the RS-232 PCBA to prevent damage to the RS-232 PCBA and its connecting wires. Use of an anti-static tape to hold the RS-232 PCBA to the Main PCBA is recommended.

4 LIft the Main PCBA off of the chassis supports and tilt it towards the back of the lower enclosure, following the precautions for the RS-232 PCBA, if applicable (Figure 5-8).

NOTE: It is not necessary to remove the chassis from the lower enclosure.

5 Disconnect the blower assembly (ITEM 7) wiring harness from the J3 connector on the Main PCBA (Figure 5-8).

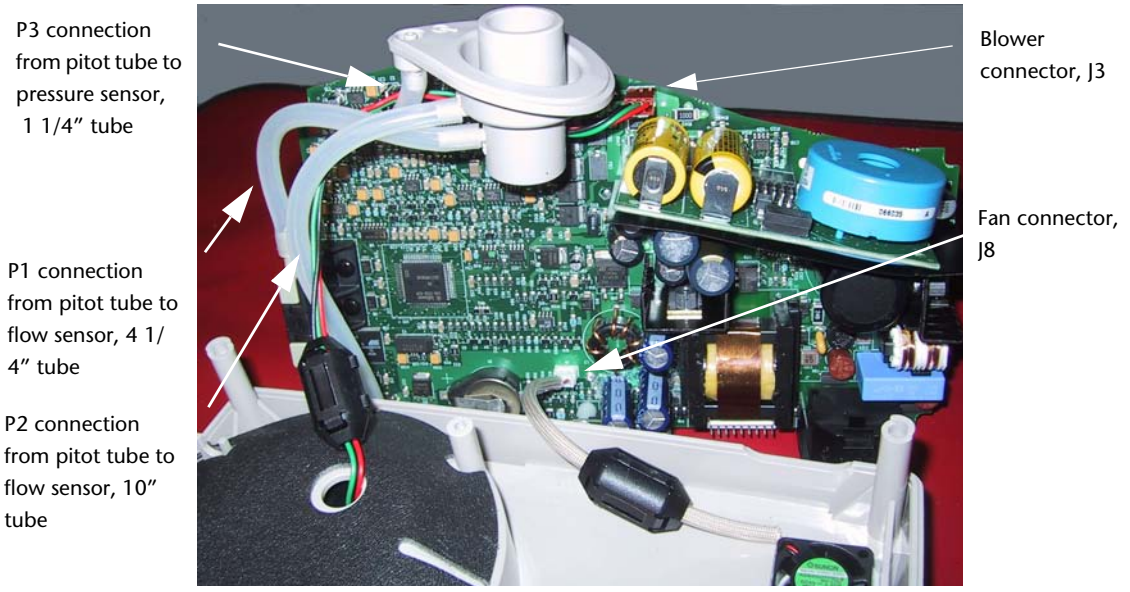


Figure 5-8. Blower, fan, and tubing connections

6 Disconnect the fan assembly (ITEM 19) wiring harness from the J8 connector on the Main PCBA (Figure 5-8).

7 Locate the Alarm PCBA, ITEM 20, and the alarm shield, ITEM 34 (Figure 5-9). Gently pull up on the Alarm PCBA and alarm shield together to remove them from the Main PCBA. Keep the alarm shield for later re-installation or replace if damaged.

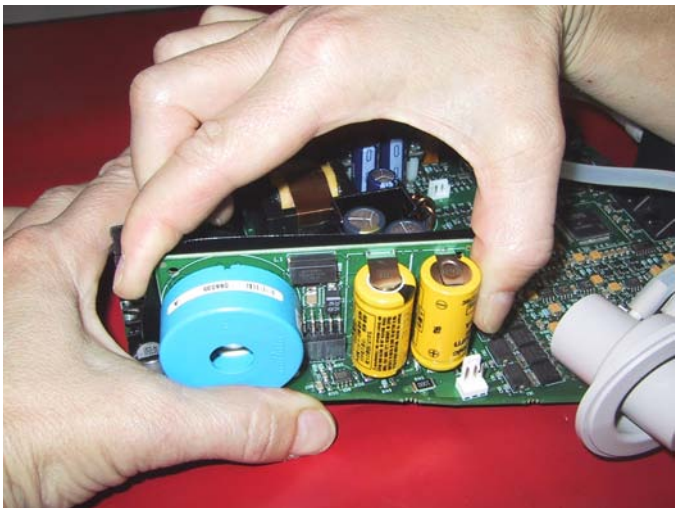


Figure 5-9. Removing the Alarm PCBA

Caution

When installing the new Alarm PCBA, ensure header pins are aligned properly with the J6 connector on the Main PCBA. Misalignment during assembly could result in severe damage and necessitate replacement of the Alarm PCBA and the Main PCBA.

8 Install the new Alarm PCBA by attaching it to connector J6 on the Main PCBA.

9 Re-install the alarm shield, ensuring that it is placed squarely between the Alarm PCBA and the Main PCBA components.

Caution

If, during disassembly, the chassis was accidentally removed from the lower enclosure and the foam pulled away, carefully re-attach the foam to the chassis so that it is not pinched in any way that occludes the blower air inlet.

10 Reconnect the fan wire to the J8 connector, and the blower wire to the J3 connector.

11 Place the Main PCBA back onto the chassis support posts, ensuring that the Alarm PCBA fits into the notches on the chassis. If necessary, slide the ferrite on the blower wiring harness so that it rests in the space near the pressure transducer (the pressure transducer is connected to the 1.25" silicone tube). This enables the Main PCBA to sit flush with the chassis support posts. Check that the Mains/AC connector rests properly in the lower enclosure and that the 10" silicone tubing rests in the carriers of the chassis as shown in Figure 5-10.

Caution

Ensure that none of the silicone tubing is pinched or kinked during re-assembly.

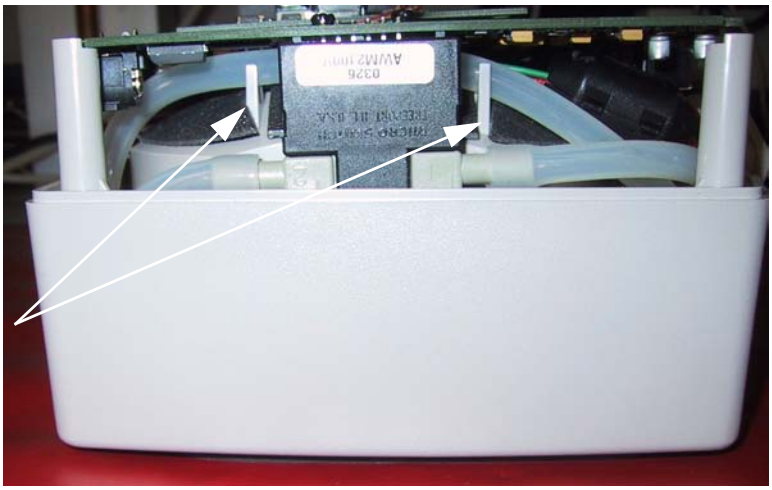


Figure 5-10. Correctly routed silicone tubing

12 Replace the RS-232 PCBA insulator shield and plastic spacers and fasten the Main PCBA onto the chassis using the screws removed in step 3. Torque screws to 5 in-lb.

13 Push the pitot tube back into the bellows and fit the pitot tube into the groove of the lower enclosure.

Caution

Ensure that the bellows does not get pushed back through the chassis at any point and that the pitot tube fits properly in the bellows.

14 Complete the assembly by performing the steps in Section 5.9.

5.8 Cooling fan assembly replacement

1 Perform steps 1-6 of Section 5.7, Alarm board assembly replacement.

2 Pull the cooling fan assembly, ITEM 19, away from the adhesive foam, ITEM 18, and then remove the foam from the chassis.

3 Open the ferrite, ITEM 8, by sliding your fingernail underneath the latch, and remove it from the fan wiring harness. Keep the ferrite for re-installation.

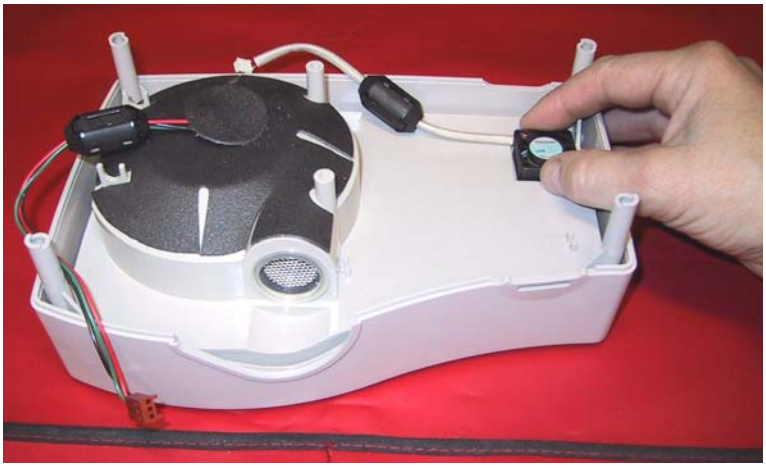


Figure 5-11. Removing the fan from the chassis

NOTE: Ensure that all of the old foam has been removed from the square recessed corner of the chassis before installing the new fan and foam assembly.

4 Apply new fan adhesive foam, ITEM 18, to the bottom of the new cooling fan assembly, ITEM 19, (side opposite the fan label).

5 Press the cooling fan assembly, adhesive side down, into the square recess in the corner of the chassis. Make sure that the wires are oriented as shown in Figure 5-11.

6 If the new fan assembly does not have a ferrite included with the assembly, attach the old ferrite to the mid-point of the fan wiring harness, by aligning the harness in the ferrite's channel and snapping it closed.

7 Perform steps 10-14 of Section 5.7 to complete the assembly.

5.9 Ventilator reassembly

1 Plug the membrane switch ribbon cable connector into the J5 header on the Main PCBA.

Caution

Be careful to align the connector and header properly.

2 Place the enclosure cover onto the ventilator assembly, and carefully align the tongue and groove portions of the cover and base and the connectors with the holes at the back of the cover. Tuck the membrane switch ribbon cable underneath the Main PCBA, and ensure that there are no wires or silicone tubing pinched between the cover and base enclosures. Ensure that the LCD is properly aligned with the membrane switch window.

Figure 5-12. Aligning the rear connectors

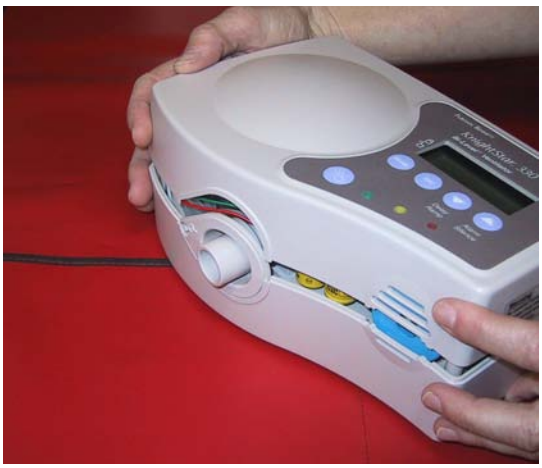


Figure 5-13. Installing the enclosure cover

3 Hold the device together and turn over so that the base is facing upward. Install four screws, ITEM 15, using a Torx® T20 driver or #2 Phillips, as required. Torque the screws to 15 in-lb.

5.10 Post-repair testing

After the *KnightStar 330* has been repaired, run the Performance Verification tests described in Section 3. Record the test results on the checklist found at the end of that section.

SECTION 6

Warranty and service information

6.1 Limited warranty

Puritan Bennett warrants to the owner that the *KnightStar 330* ventilator, exclusive of expendable parts and other accessories, shall be free from defects in material and workmanship for twelve months from the original date of sale. Puritan Bennett's sole obligation, with respect to any such defect, is limited to the repair, replacement of parts, or, at Puritan Bennett's option, replacement of the ventilator. Purchaser pays return freight charges.

This warranty is made on the condition that prompt notification of a defect is given to Puritan Bennett within the warranty period, and that Puritan Bennett has the sole right to determine whether a defect exists.

The warranty does not apply to ventilators that have been partially or completely disassembled or repaired by unauthorized personnel, or serviced or repaired by qualified personnel in any manner other than that described in the Service Manual; altered; subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by Puritan Bennett.

This warranty represents the exclusive obligation of Puritan Bennett and the exclusive remedy of the purchaser regarding defects in the ventilator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY AS TO THE KNIGHSTAR 330 VENTILATOR, AND IS GIVEN IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY ORAL OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

No person is authorized to modify, in any manner, Puritan Bennett's obligation as described above.

6.2 Service information

KnightStar 330 ventilators are warranted against defects in workmanship and materials. Do not make any service repairs on this equipment during the stated warranty period. Any unauthorized work immediately voids the warranty. If you need information or assistance, or if the information in this manual is insufficient, contact Puritan Bennett Technical Support at: 1.800.255.6774 (for North America). Outside the US, contact your local representative.

Puritan-Bennett Corporation does not recognize the owner of a ventilator as an authorized trained service representative. Puritan Bennett will not be liable for any repairs attempted by the owner. Any such attempted repairs other than specified non-warranty repairs void the warranty. Parts and labor costs incurred by the owner will not be reimbursed by Puritan Bennett. Puritan Bennett will make available upon request diagrams, component parts lists, descriptions, calibration procedures and instructions to assist in the repair of parts classified by Puritan Bennett as repairable.

Returns should be processed through your local representative.

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